EXHIBIT C

CT Corporation

Service of Process Transmittal
07/06/2018
CT Log Number 533647551

TO: Andrea Alfano
Allergan, Inc.
5 Giralda Farms
Madison, NJ 07940-1027

RE: **Process Served in Missouri**

FOR: ALLERGAN USA, INC. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	ELIZABETH CROCKER, ET AL., PLTFS. vs. ALLERGAN USA, INC., ET AL., DFTS.
DOCUMENT(S) SERVED:	SUMMONS, REQUEST, PETITION
COURT/AGENCY:	21st Judicial Circuit Court, St. Louis County, MO Case # 18SLCC2047
NATURE OF ACTION:	Medical Injury - Improper Care and Treatment
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Clayton, MO
DATE AND HOUR OF SERVICE:	By Process Server on 07/06/2018 at 11:10
JURISDICTION SERVED :	Missouri
APPEARANCE OR ANSWER DUE:	within 30 days after receiving this summons, exclusive of the day of service
ATTORNEY(S) / SENDER(S):	Christopher W. Dysart THE DYSART LAW FIRM, P.C. 16020 Swingley Ridge Rd., Ste. 340 Chesterfield, MO 63017 636-590-7110
ACTION ITEMS:	CT has retained the current log, Retain Date: 07/07/2018, Expected Purge Date: 07/12/2018 Image SOP Email Notification, Taylor Reynolds Taylor.Reynolds@allergan.com Email Notification, Marc Singer Marc.Singer@allergan.com Email Notification, Andrea Alfano andrea.alfano@allergan.com Email Notification, Chris Garber garber_chris@allergan.com
SIGNED:	C T Corporation System
ADDRESS:	120 South Central Avenue Suite 400 Clayton, MO 63105
TELEPHONE:	314-863-5545

IN THE 21ST JUDICIAL CIRCUIT COURT, ST. LOUIS COUNTY, MISSOURI

Judge or Division: DAVID L VINCENT III	**Case Number: 18SL-CC02047**
Plaintiff/Petitioner: ELIZABETH CROCKER vs.	Plaintiff's/Petitioner's Attorney/Address CHRISTOPHER W DYSART SUITE 340 16020 SWINGLEY RIDGE RD CHESTERFIELD, MO 63017
Defendant/Respondent: ALLERGAN USA, INC.	Court Address: ST LOUIS COUNTY COURT BUILDING 105 SOUTH CENTRAL AVENUE CLAYTON, MO 63105
Nature of Suit: CC Pers Injury-Prod Liab	(Date File Stamp)

Summons in Civil Case

The State of Missouri to: ALLERGAN USA, INC.
Alias:
R/A: CT CORPORATION SYSTEM
120 SOUTH CENTRAL AVENUE
CLAYTON, MO 63105

COURT SEAL OF
ST. LOUIS COUNTY

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

26-JUN-2018
Date

Clerk

Further Information:
JJ

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to

_____ (name) _____ (title).

☐ other _____.

Served at _____ (address)

in _____ (County/City of St. Louis), MO, on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____ Date

_____ Notary Public

Sheriff's Fees, if applicable

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE CIRCUIT COURT OF ST. LOUIS COUNTY
STATE OF MISSOURI
TWENTY-FIRST JUDICIAL CIRCUIT

ELIZABETH CROCKER,
STACEY HACKMAN, and
AMY ROBERTS,

Plaintiffs

v.

ALLERGAN USA, INC.

Serve at: CT Corporation System
120 South Central Ave.
Clayton, MO 63105

APOLLO ENDOSURGERY US, INC.

Serve at: National Registered Agents, Inc.
120 S. Central Avenue
Clayton, MO 63105

JAMES S. SCOTT, M.D.

Serve at: 2000 SE Blue Parkway, Suite 120
Lees Summit, MO 64063

ST. LOUIS BARIATRIC SPECIALISTS LLC

Serve at: Darin M. Minkin, Inc.
c/o Darin M. Minkin
1211 Devonworth Drive
Town and County, MO 63017

DR. DARIN M. MINKIN

Serve at: 1211 Devonworth Drive
Town and County, MO 63017

Cause No: 18SL-CC02047

Division: 9

JURY TRIAL REQUESTED

and

DES PERES HOSPITAL, INC.

Serve at: The Corporation Company
120 South Central Avenue
Clayton, MO 63105

Defendants.

FIRST AMENDED PETITION

COME NOW Plaintiffs, Elizabeth Crocker, Stacey Hackman, and Amy Roberts, by and through their undersigned attorneys, and for their Petition, state as follows:

PARTIES

I. Plaintiffs

1. Plaintiff Elizabeth Crocker (hereinafter, "Crocker") is a resident of Illinois. The conduct that gives rise to her cause of action arose in St. Louis County, Missouri, in that the Lap-Band® device, Lap-Band® AP Standard with Access Ports, Catalog No.: B-2240, Serial No.: 13049816, Model No.: B-2240 was caused to be implanted in Plaintiff Crocker at DePaul Hospital, located in St. Louis County, by Defendant Scott, on or about December 7, 2007, and/or on or about February 8, 2015, the Lap-Band® device was caused to be surgically removed from Crocker at Defendant, Des Peres Hospital, located in St. Louis County, Missouri.

2. Plaintiff Stacey Hackman (hereinafter, "Hackman") is a resident of Missouri. The conduct that gives rise to her cause of action arose in St. Louis County, Missouri, in that the Lap-Band® device Lap-Band® AP Large with Access Port I, Ref.: B-2245, Serial No.: 4751131, was caused to be implanted in Hackman at Defendant, Des Peres Hospital, by Defendant Minkin located in St. Louis County, on or about February 25, 2010, and/or on or about

August 5, 2015, the Lap-Band® device was caused to be surgically removed from Hackman at Defendant, Des Peres Hospital, located in St. Louis County, Missouri.

3. Plaintiff Amy Roberts (hereinafter, "Roberts") is a resident of Missouri. The Lap-Band® device 9.75cm Adjustable Gastric Banding System Catalog No.: B-2210, Serial No.: 5011 B150-127 was caused to be implanted in Plaintiff Roberts at St. Joseph Hospital, located in St. Charles County, on or about March 5, 2002. The conduct that gives rise to her cause of action arose in St. Louis County, Missouri, in that on or about December 5, 2014, the Lap-Band® device was caused to be surgically removed from Roberts at Defendant, Des Peres Hospital, located in St. Louis County, Missouri.

4. Hereinafter, all plaintiffs set forth above will be collectively referred to as "Plaintiffs."

II. Defendants

5. Defendant ALLERGAN USA, INC. (hereinafter, "Allergan") now is, and at all times relevant to this action was, a for-profit corporation, incorporated under the laws of the State of Delaware. Allergan is a multi-specialty healthcare company with its principal place of business located at 2525 Dupont Drive, Irvine, California 92612. Defendant Allergan is authorized to and does business throughout the State of Missouri, and Allergan, in fact, does business throughout the State of Missouri.

6. In approximately 2006, Allergan acquired the Lap-Band® System with its purchase of Inamed Corporation. The purchase included BioEnterics Corporation, a subsidiary that was responsible for introducing the Lap-Band® System product line to the United States. BioEnterics Corporation had previously sold an adjustable gastric banding system for morbid obesity in Europe and Australia. Since 2006, Allergan has been engaged in the business of designing, testing, manufacturing, assembling, packaging, labeling, distributing, selling, and

marketing the Lap-Band® for use by surgeons performing surgical operations of members of the general public. In 2013, Allergan USA, Inc. sold the rights to the Lap-Band® System to Defendant Apollo Endosurgery, Inc.

7. Defendant APOLLO ENDOSURGERY US, INC. (hereinafter, "Apollo") now is, and at all times relevant to this action was, a for-profit corporation, incorporated under the laws of the State of Delaware. Apollo is a medical device company focused on less invasive therapies for the treatment of obesity with its principal place of business located at 1120 South Capital of Texas Highway #300, Austin, Texas 78746. Defendant Allergan is authorized to and does business throughout the State of Missouri, and Apollo, in fact, does business throughout the State of Missouri.

8. In approximately October 2013, Apollo purchased Defendant Allergan's obesity intervention division for up to $110 million, which included the Lap-Band® product line.

9. Defendant JAMES S. SCOTT, M.D. is a duly licensed medical doctor and, upon information and belief, is a Kansas resident.

10. Defendant ST. LOUIS BARIATRIC SPECIALISTS, LLC is a Missouri Limited Liability Company, licensed to do business in the State of Missouri with its principal place of business within the State of Missouri.

11. Defendant, DR. DARIN M. MINKIN, is a duly licensed physician and a Missouri resident.

12. Des Peres Hospital, Inc., d/b/a/ Des Peres Hospital is upon information and belief, a Missouri Corporation with its principal place of business in the State of Missouri.

13. Hereinafter, Apollo and Allergan will be referred to collectively as "Lap-Band® Defendants". Hereinafter, all defendants set forth above will be collectively referred to as "Defendants." Defendant, James S. Scott, M.D., Dr. Darin M. Minkin, St. Louis Bariatric

Specialists, LLC and Des Peres Hospital will collectively referred to as "Medical Defendants".

JURISDICTION AND VENUE

14. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, this Court has specific in *personam* jurisdiction over the Lap-Band® Defendants and Medical Defendants, because the Lap-Band® Defendants are present or domiciled in the State of Missouri, the Medical Defendant are present or domiciled in the State of Missouri, and the torts giving rise to Plaintiffs' causes of action occurred within the State of Missouri such that requiring in appearance does not offend traditional notions of fair play and substantial justice.

15. This Court has specific personal jurisdiction over the Defendants, pursuant to and consistent with, Section 506.500, RSMo, and the Constitutional requirements of Due Process, in that the Defendants, individually or acting through their apparent agents, committed one or more of the following acts within the State of Missouri:

    i The Defendants transacted business in the State of Missouri, Section 506.500.1(1), RSMo;

    ii The Defendants made or performed a contract or promise substantially connected with and/or within the State of Missouri, Section 506.500.1(2), RSMo;

    iii The Defendants committed, and/or conspired to commit, tortious acts within the State of Missouri, Section 506.500.1(3), RSMo;

    iv The Defendants owned, used, or possessed real estate situated in the State of Missouri, Section 506.500.1(4), RSMo;

v At all relevant time, it was foreseeable to the Defendants that their tortious acts and/or their transaction of business in the State of Missouri would have consequences such that Defendants could reasonably foresee being hauled into Court in the State of Missouri; and

vi Requiring the Defendants to litigate this claim in Missouri does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

16. The Lap-Band® Defendants, at all relevant times, have engaged in substantial business activities within the State of Missouri. At all relevant times the Lap-Band® Defendants transacted, solicited, and conducted business in Missouri through their employees, agents, and/or sales representatives, and the Lap-Band® Defendants derived substantial revenue from such business by marketing the Lap-Band® to people of the State of Missouri.

17. The Lap-Band® Defendants had substantial contacts with physicians in Missouri including, based upon information and belief, contacts through marketing to physicians to encourage physicians to use the Lap-Band® device and marketing of the product to consumers, including plaintiffs, within the State of Missouri.

18. There is no federal subject matter jurisdiction because there is no federal question raised. Plaintiffs' claims in this action are brought solely under Missouri law. To the extent Plaintiffs rely upon federal law or regulation governing the design, manufacture, and/or sale of a medical device, Plaintiffs do so for the purposes of properly pleading "parallel" state law claims as recognized by the Supreme Court of the United States. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

19. Venue is proper in this county in accordance with Section 508.010.4 and Section 508.010.9 of the Missouri Revised Statutes because the conduct that gave rise to Plaintiffs' causes of action occurred in St. Louis County, Missouri, and each Plaintiff was first injured by the wrongful acts of the Lap-Band® Defendants in St. Louis County.

20. The claims in this case present common questions of law concerning, *inter alia*, what information the Lap-Band® Defendants possessed concerning the harmful consequences of implanting the Lap-Band® device in a human, what information the Lap-Band® Defendants possessed concerning the unsafe and injurious design and manufacture of the Lap-Band® device, what information the Lap-Band® Defendants elected to disclose to physicians and patients about those harmful, unsafe, and/or injurious effects, and what information Lap-Band® Defendants were required by law to disclose about those effects. Plaintiffs herein are properly joined pursuant to the Missouri Rule on permissive joinder, Rule 52.05(a). The Lap-Band® Defendants' wrongful conduct is common to all three Plaintiffs who have suffered injury from the purchase and implanting of the Lap-Band® device. Said differently, the Plaintiffs' claims against the Lap-Band® Defendants arise from the same transaction or occurrence or series of transactions or occurrences.

21. Joinder is consistent with Rule 52.05(a), Rule 66.01, the State of Missouri correlatives to Federal Rules of Civil Procedure 20 and 42, and will permit this Court to sever matters if deemed necessary for trial or make such other orders as may be necessary to prevent delay or prejudice or to promote expedition and judicial economy.

22. Joinder of the Lap-Band® Defendants, with the Medical Defendants is proper in this case under Missouri law, including Rule 52.05(a) and Rule 66.01, in that both sets of Defendant's were involved in the same transaction or series of transactions including, but not limited to,

failing to warn Plaintiff's that the Lap-Band® procedure had a higher than 1% Lap-Band® erosion rate, was not as safe and effective as gastric bypass, should not be used as a "rescue" procedure in the event of a previous failed bariatric surgery involving an implanted device or that in the event of a previous failed bariatric implant surgery the Lap-Band® procedure was more likely to fail and/or lead to Lap-Band® erosion.

UNDERLYING COMMON FACTS AS TO ALL DEFENDANTS

I. The Lap-Band® System and Bariatric Weight Loss Surgery

The gastric bypass was invented by Dr. Edward Mason, a surgeon from the University of Iowa, in 1967. Mason had observed that patients with peptic ulcer disease often – though unintentionally - lost weight after undergoing surgery to have part of their stomach removed. Interested in applying this to obese persons, yet concerned removal of the stomach would cause ulcers, Mason developed what would later became recognized as the "gold standard" in bariatric surgery, the gastric bypass. This surgery - first tested on dogs - involved stapling the top part of the stomach to create a small pouch; the pouch was then attached to the jejunum, the upper part of the small intestine, to provide intestinal continuity, while the remaining 'bypassed' stomach was left in place. The Roux-en-Y modification - which involved lengthening the Roux limb to improve weight loss and use of retrocolic and retrogastric routing to ease some of the technical challenges - was first performed in 1977. Various modifications were made to the techniques over time and surgery centers began offering the surgery in varying forms.

Standardization of the procedure and the long-term follow-up studies of patients who underwent the procedure began in the 1980s; Dr. Walter Pories standardized the size of the gastric pouch and the length of the retrocolic, retrogastric Roux-en-Y gasrojejunostomy. Dr. Pories also measured the weight loss, complication rate, and glucose level and impact on

obesity-related co-morbidities of more than 600 patients over a 14-year period, among the first study of its kind to monitor bariatric patients over time. Over the years, the technique has evolved and become more standardized.

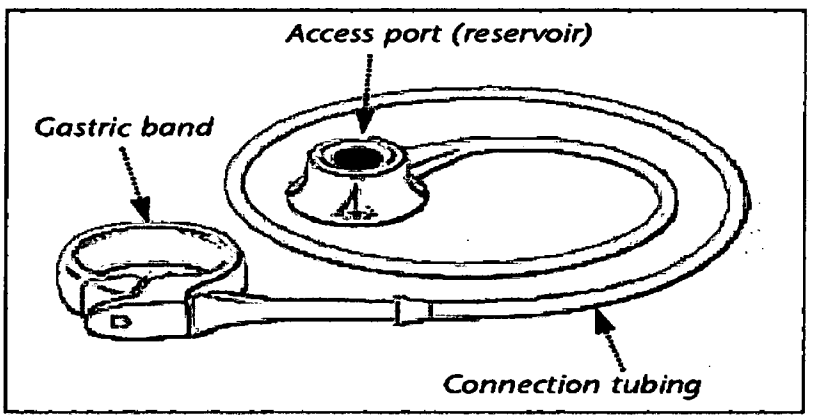
From Fixed to Adjustable: The Design and Evolution of the Gastric Band.

Created partly as a solution to the complications presented from malabsorptive and combination procedures, the gastric band was seen as a less-invasive way to achieve weight loss among the obese. However, the original gastric band - designed initially to be non-adjustable – had poor weight loss outcomes and its own set of complications unique to the material and the surgical placement of the restrictive device. Like its other bariatric surgery counterparts, the surgical technique and the design of the gastric band has changed numerous times since the late 1970s, evolving from a nonadjustable device initially made of Marlex mesh and later Dacron graft to an adjustable, silicon band placed around the upper part of the stomach.

By 1983, the material of the band was universally adopted as surgeons believed silicon was a safer implantable material and caused less tissue damage. But the switch to an *adjustable* band didn't occur until the mid-1980s. The original nonadjustable band required the use of an electronic calibrating device to determine where along the stomach the band should be placed to create an ideal stoma size. But reports of slippage - where the stomach prolapses either anteriorly or posteriorly through the band - erosion of the band into the stomach, esophageal dilation, and weight regain were common with the nonadjustable band, often requiring provisional surgery; surgeons soon determined that it was nearly impossible to create an ideal stoma diameter during surgery, despite changes to the calibrating devices to achieve more precision perioperative.

23. The Lap-Band®, a form of adjustable gastric band, was first introduced in Europe in and around 1993. Lap-Band® Defendants were granted pre-market approval for the Lap-Band® by the FDA in and around June 2001. The Lap-Band® is a Class III medical device designed as a long-term, surgically implantable device intended to induce weight loss in morbidly obese patients by limiting food consumption. The Lap-Band® is manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by the Lap-Band® Defendants.

24. The Lap-Band® components include the silicone elastomer band, an access port, and tubing used to connect the band and port, as shown below.



The LAP-BAND Adjustable Gastric Banding System

25. At all times relevant to this Petition, in order to be eligible for a the Lap-Band® device, patients were supposed to have a Body Mass Index (BMI) of at least 40 or a BMI of 35 with at least one obesity-related health condition, or those who are 100 pounds over their ideal weight. Patients were also supposed to have been overweight for more than 5 years and have previously failed more conservative weight loss techniques. Those who undergo the

procedure must be prepared to make extreme changes in eating habits and lifestyle for the remainder of their lives.

26. During surgery, a surgeon wraps the band around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrow opening of the stomach pouch (stoma) limits how quickly food passes to the lower part of the stomach. Fullness is supposed to be achieved with just a small amount of food.

II. Legal History of the Lap-Band®

27. The Medical Device Amendments of 1976 (DA"), 21 U.S.C. § 360c, *et seq.*, to the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, "impose[] a regime of detailed federal oversight" administered by the Food and Drug Administration ("FDA").

28. Class III devices are those that "present a potential, unreasonable risk of illness or injury," among other things.

29. Premarket Approval ("PMA") is the process the FDA uses to evaluate the safety and efficacy of medical devices, such as the Lap-Band®.

30. PMA applications can contain thousands of pages of information. A PMA application must include the device's indications for use, description, marketing history, manufacturing process, and a summary of studies, just to name a few. *See* 21 C.F.R. § 814.20.

31. The FDA may grant PMA for a medical device only if it finds, *inter alia*, that:

    a. There is a "reasonable assurance" of the device's "safety and effectiveness" under the conditions of used included in the proposed labeling for the device; *and*

    b. The proposed labeling is neither false nor misleading. 21 U.S.C. § 360e(d)(1)(A), (2)(A), (B), and (D).

32. Once a device receives PMA, it "may not be manufactured, packaged, stored, labeled, distributed or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80.

33. The Lap-Band® System has been in use in Australia and Europe since 1993. Over 750,000 The Lap-Band® Systems have been distributed globally, and it has been widely reported on in medical literature.

34. The Lap-Band® Defendants initially sought FDA PMA in the late 1990s. On or about March 24, 2000, BioEnterics Corporation, a subsidiary of Inamed Corporation, submitted its application for PMA of the Lap-Band® system with the Food & Drug Administration (FDA).

35. Initial PMA was denied by the Center for Devices and Radiological Health ("CDHR") in August 2000, following the recommendation of the Gastroenterology and Urology Devices Panel. The denial was based on inadequate clinical support for the safety and efficacy of the device and inadequate safety information regarding esophageal dilation. CDHR recommended expanded follow-up, updated and/or amended device labeling, and post-approval study.

36. On June 5, 2001, the FDA approved BioEnterics PMA application with a list of conditions that it had to fulfill in order to maintain The Lap-Band® approval. These conditions included:

    a. The submission of periodic reports, required under 21 C.F.R. 814.84, at intervals of one year from the date of approval of the original PMA. Pursuant to the PMA and 21 C.F. R. 814.84, Lap-Band ® Defendants were required to file a summary and bibliographs of the following:
        1. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonable should be known to the applicant; and
        2. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.

b. The submission of "Adverse Reaction and Device Defect Reporting". As noted in the 2001 PMA approval letter to BioEnterics Corporation, the FDA determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Lap-Band® Defendants were required to submit "Adverse Reaction Reports" or "Device Defect Reports" to the FDA. The Lap-Band® Defendant were required to submit the reports within 10 days after the Lap-Band® Defendants receives or has knowledge of information concerning:

    a) Any adverse reaction, side effects, injury, toxicity or sensitivity reaction that is attributable to the device, and
        i. Has not be addressed by the devices labeling or,
        ii. Has been addressed by the devices labeling but is occurring with unexpected severity or frequency.

c. Reporting adverse events under the Medical Device Reporting (MDR) Regulation if the Lap-Band® may "have caused or contributed to a death or serious injury; or [h]as malfunctioned and...would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;" and

d. Include in its Annual Report any failures of the device that meet the specifications outlined in the PMA that would have been correctable by procedures described in the Lap-Band® labeling.

e. The Lap-Band® Defendants were also instructed by the FDA that: A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidents of anticipated adverse effects, or device failures necessitates a labeling, manufacturing or device modification.

37. In addition to the Annual Report requirements, the Lap-Band® Defendants were also required to complete two post approval studies that evaluated the long-term effectiveness of the device and the incidence of adverse events. The Lap-Band® Defendants were also required to ensure that their representations and warranties were consistent with both Federal and State law.

38. Notwithstanding the conditions of approval outlined in the PMA, the Lap-Band® Defendants were also required to comply with all state and federal laws, including but not limited to:

a. **21 C.F.R. § 803.50, *et seq.*:** The Lap-Band® Defendants were required to report to the FDA no later than thirty calendar days after the day the Lap-Band® Defendants receive or become aware of information suggesting that the Lap-Band® caused or contributed to a death or serious injury. The Lap-Band® Defendants must also report to the FDA if the Lap-Band® had malfunctioned, and that malfunction would be likely to cause death or serious injury if it were to reoccur. The Lap-Band® Defendants must conduct an investigation of the malfunction and determine the cause.

b. **21 C.F.R. § 814.80:** The Lap-Band® Defendants were required to manufacture the Lap-Band® device "according the approved specifications for the medical device[.]"

c. **21 C.F.R. § 814.82(a)(9):** The Lap-Band® Defendants were required to continuously evaluated and report on the safety, and reliability of the Lap-Band® for its intended use.

d. **21 C.F.R. §§ 820.20, 820.100:** The Lap-Band® Defendants were required to establish a quality management policy and instructions with respect to the Lap-Band®, including the development of corrective and preventive action (CAPA) procedures to address nonconformance and quality issues.

e. **21 C.F.R. § 820.30:** The Lap-Band® Defendants were required to establish and maintain procedures for validating the design of the Lap-Band® that includes testing individual units under actual or simulated conditions, creating a risk plan, and conducting risk analyses.

f. **Current Good Manufacturing Practices (CGMP):** The Lap-Band® Defendants were required to follow quality systems to help ensure that the Lap-Band® product consistently met applicable requirements and specifications.

39. The Lap-Band® Defendants generally had the ability to unilaterally update the Lap-Band® labeling to include any newly acquired information regarding safety, without prior approval of the FDA 21 C.F.R. § 814.39(d). The permitted changes to the label include:

g. Any label change that strengthens or adds contraindications, warnings, or adverse reactions that have reasonable evidence of a causal association;

h. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

i. Labeling changes that delete misleading, false, or unsupported indications; and

j. Labeling changes that reflect changes in quality controls or manufacturing processes that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

40. Not only did the Lap-Band® Defendants have the ability to unilaterally update the Lap-Band® Labeling, the PMA for the Lap-Band® specifically required that the Lap-Band® Defendants provide supplemental warnings if unanticipated adverse effects, increases in the incidences of anticipated adverse effects, or device failures necessitates a labeling, manufacturing or device modification. The PMA for the Lap-Band® specifically provides:

> A PMA Supplement **must** be submitted when unanticipated adverse effects, increases in the incidences of anticipated adverse effects or device failures, necessitates a labeling manufacturing or device modification. ***(emphasis added)***

41. While the Lap-Band® has been sold in the United States since 2001, it didn't explode into the marketplace until Allergan's $3.2-billion acquisition of breast implant maker Inamed Corp. in 2006. Although Allergan bought Inamed for its portfolio of cosmetic medical devices, the company "quickly realized the real jewel was Lap-Band®." Shortly after the acquisition, Allergan rolled out an extensive direct-to-consumer advertising campaign for the LAP-BAND – an unusual tactic for a medical device. Allergan's campaign included a television commercial featuring a distressed woman trying to "tame" *a* roaring lion pulling her into a refrigerator. Within a week of launching the campaign, visits to Allergan's Lap-Band® website increased nearly fivefold and sales of the device soared 50% to $270 million in 2007. Defendant Allergan rolled out a new multimillion-dollar Lap-Band® campaign in 2008, targeting its commercials to female audiences of daytime soap operas. Allergan also signed a co-marketing pact with Covidien, Ltd., to, among other things, scout out surgeons to entice with making money conducting Lap-Band® surgeries.

At all times relevant to this Petition, Allergan's marketing efforts successfully, although untruthfully, positioned the Lap-Band® as a safer but just as effective a weight loss method compared to gastric bypass. At all times relevant to this Petition, Allergan marketed the Lap-Band® as a "cure your hunger", diets and exercise don't work, and lose weight fast, easy and safe procedure. Some bariatric surgeons also got on the Lap-Band® train because they saw it as a way to make money fast instead of doing a gastric bypass procedure which has a lower long-term complication rate and is more effective at weight loss and curing co-morbidities, because they could only perform 3 gastric bypass in a day compared to 7 Lap-Band®

surgeries in a day and the reimbursement rate from insurance companies was relatively the same.

42. On April 27, 2010, Allergan, Inc. submitted its application for PMA supplement for the Lap-Band® Adjustable Gastric Banding System with the Center for Devices and Radiological Health (CDRH) of the FDA. The supplement was submitted to expand the indication (people eligible) for the Lap-Band® Adjustable Gastric Banding System. Because of this expansion of potential eligible patients, the Lap-Band® Defendants estimated more than 26 million Americans would be newly eligible for surgery.

43. On February 16, 2011, the CDRH approved the PMA supplement for the Lap-Band® Adjustable Gastric Banding System. The Lap-Band® Defendants were required to complete the same requirements as when they were first approved, mentioned above.

44. From March 2012 to September 2015, the FDA cited the Lap-Band® Defendants for inadequate post-approval studies. For the six month to four year reports, culminating a total of six reports, the Lap-Band® Defendants studies were only "On Time" once. The five other times, the report was "Overdue." Overall, the follow-up rate was below 80%.

III. Lap-Band® Defendants Go Rogue

45. Lap-Band® Defendants have at all times material to this Petition publically stated though aggressive T.V., Internet and written advertisement that the Lap-Band® is "safer but just as effective as gastric bypass", "up to 10 times safer than gastric bypass" that the Lap-Band® procedure is the "[o]nly surgical option designed to maintain long-term weight loss," and that the Lap-Band® system has "fewer risks and side effects" than gastric bypass. None of these statements were approved by the FDA nor were they part of the FDA approved labeling. Most importantly, all of these statements are demonstrably false.

46. Lap-Band® Defendants have also stated through their T.V., Internet and print advertising that the total number of complications for the Lap-Band® procedure are 9% while the total number of complications for gastric bypass are 23%, that major complication for the Lap-Band® procedure are 0.2% while major complication for gastric bypass are 2.1%. Additionally, Defendant Allergan in its 2007 www.Lapband.com Website describes the complication of Lap-Band® erosion as requiring "minor revisional surgery". Defendant Allergan makes this false claim to compare the Lap-Band® System to gastric bypass's complications of the "separation of stapled areas" or "leaks from staple lines" which Defendant Allergan describes as requiring "major revisional surgery".

Defendant Allergan's promise that band erosion requires only "minor revisional surgery" is directly contradicted by the way band erosion is described in the warning label approved by the FDA which states that band erosion is a "serious adverse event", that "[r]e-operation to remove the devise is required', and that "[r]e-operation for band erosion may result in gastrectomy" – that is surgical removal of part or all of the stomach. Defendant Allergan's statement that the complication of band erosion requires only "minor revisional surgery" was never approved by the FDA and is, in-fact, a lie.

Lap-Band® Defendant's statement that the Lap-Band® has only a 9% total complication rate was never approved by the FDA and, is once again, directly contradicted by not only numerous medical studies, but by information that Lap-Band® Defendants conveyed directly to the FDA in seeking approval to sell the Lap-Band®. Lap-Band® Defendant stated that in the results of their clinical trial 89% of the subjects reports at least one adverse event,

including 17% of the patients having to have their Lap-Band® removed. Moreover, thirty-four percent (34%) of patients in the clinical study submitted to the FDA reported at least one "severe adverse event". Lap-Band® Defendants and the FDA define a "severe adverse event" as causing "severe discomfort such that patient cannot perform daily activities. Severity may result in cessation of treatment or required removal of the device, or treatment of symptoms may be given and/or patient hospitalized".

In support of Lap-Band® Defendants contention that the Lap-Band® has only a 9% total complication rate they cite one article - - O'Brien P, Dixon J. Lap-Band®: *Outcome and results, J. of Laparoendosc & Adv. Surg. Techniques*, 13(4), 2003, 265-270. First, Lap-Band® Defendants citing only medical articles that support its contention when there are numerous medical articles concluding the total complication rate is much higher than 9% including the clinical study they submitted to obtain FDA approval is prohibited by 21 C.F.R. § 99.101 which allows a manufacturer to disseminate written information concerning the safety or effectiveness of the device that is not described in the labeling only if, among other things, it is not "false or misleading" 21 C.F.R. § 99.101(a)(4). Moreover, information can be considered fake or misleading", "if, among other things, the information includes only favorable publications when unfavorable publications exist…" 21 C.F.R. § 99.101(a)(4).

The Lap-Band® Defendants marketing statement that there is an only 9% total complication rate not only contradicts the information they gave to the FDA, it is contradicted by numerous medical studies, some of which are described below. Moreover, the medical article they cite to support the contention of a 9% complication rate's lead author, Dr. Paul O'Brien, has received funding from Defendant Allergan, and was the National Medical Director of the Texas based True Results Clinics which launched an extensive television

marketing campaigns for the Lap-Band® and had a vested financial interested in promoting the effectiveness of the device.

47. Numerous medical studies indicate that Lap-Band® Defendants knew or should have known that the Lap-Band® had higher serious adverse event rates, including band erosion, re-operations rates and band removal and failure rates than those they reported to the FDA at the time of PMA and thereafter. Moreover, these medical studies indicate that the Lap-Band® was not as effective or as safe as gastric bypass, directly contradicting, advertising statements made by Lap-Band® Defendants. For instance, the Lap-Band® label indicates that there is only a 1% rate of band erosion. Similarly, the Lap-Band® brochure titled "*A Surgical Aid in the Treatment of Morbid Obesity: Lap-Band® Adjustable Gastric Banding System Information for Patients*", which was reviewed by the FDA at the time of the 2001 PMA, states that "the band can erode into the stomach. This can happen right after surgery or years later **although this rarely happens." (emphasis added)**[1].

48. In 2000, a study was published that showed a 3% rate of Lap-Band® erosion. *De Jonge, I.C.D.Y.M, Gie Tan, K § Oostenbrook, R.J. Obes. Surg. 2000; 10: 26-32.*

In the study, the authors note that they began using the Lap-Band® with their patients beginning in 1994 (in Italy). *Id. at 26-27.* The study gathered the results of all patients that underwent the Lap-Band® procedure between 1996 and 1998. *Id. at 27.* The study noted that "[m]ajor complications occurred in …21% of [the Lap-Band® patients]". *Id. at 27.* Three patients became septic requiring reoperation. Two of the patients had a perforation of the stomach. Both of these patients died after long stays in the Intensive Care Unit. *Id. at 27.*

[1] Plaintiff Roberts reviewed and relied upon this brochure prior to her Lap-Band® implant in 2002. Similarly, Plaintiff Hackman was led to believe that Lap-Band® erosion, the chances of re-operation and Lap-Band® removal were highly unlikely based upon statements from Dr. Minkin prior to her surgery.

The study authors state that use of the Lap-Band® produces "many minor and major complications." *Id. at 30.* "The question arises" according to the author of whether a bariatric surgeon should "accept these complications or should we investigate the other techniques in gastric restrictive surgery, which might produce fewer complications." *Id. at 30.* Along that line, the study found a Lap-Band® reoperation rate of 22% and noted other studies had found a reoperation rate of 35%. *Id. at 30.*

In the study, the authors found a 3% rate of Lap-Band® erosion where "subsequent migration of the Lap-Band® through the stomach wall occurred". *Id. at 31.*

The study authors note that "[d]uring the First International Symposium on Laparoscopic Obesity Surgery in Naples in 1999, there were reports from different countries describing migration of the [Lap-Band®]." *Id. at 31.* The study authors go on to state:

> Migration of a prosthesis is a severe and potentially lethal complication. There are multiple reports of the formerly used Angelchik esophageal anti-reflux prosthesis migrating to a variety of locations, all occurring approximately 6 to 12 months after placement. This led to the removal of the Angelchik prosthesis from the market. According to *Oria, [Oria HE, Brolin RE, Performance Standards in Bariatric Surgery. Eup J. Gastroenterol Hepatol 1999; 11: 77-84*] we have to describe on a scientific basis all complications which occurs, in relation to the time period of follow-up and the number of patients in the follow-up period.
>
> ....
>
> We urge all gastric restrictive surgeons to accurately record this specific complication among other complications in order to achieve an honest assessment [of the Lap-Band®]. *Id. at 31.*

49. In August 2001, (Lap-Band® PMA was granted in June 2001) a study was published which found a 7.5% rate of Lap-Band® erosion, *Silecchia, G., Restuccia, A., et al., Surg. Lap, Endo Percut. Tech 2001; 11(4):229-234.*

The study starts off by noting that the erosion of gastric bands made of various material (marlex, silastic, polypropylene, and polytetrafluoroethylene) have been reported after procedures such as the Angelchik anti-reflux operation or vertical banded gastroplasty. *Id. at 229.* "Migration (erosion, penetration or entrapment) of the silicone ring into the gastric lumen also has been reported after [the Lap-Band®] the incidence of adjustable prosthesis migration ranges between 0% and 11%". *Id. at 229.*

In the current study, band migration was observed in … 7.5% of patients. *Id. at 231.* "In all patients, the diagnosis was established by endoscopy between 10 and 41 months after surgery (mean 20.6 months)". *Id. at 231.* "No patients had specific symptoms or acute signs at the time of diagnosis". *Id. at 231.*

The study authors noted that "band migration is one of the major late complications of [the Lap-Band®]". *Id at 232.* "Band migration is a slow process and early detection can be achieved only by upper gastrointestinal endoscopy." *Id. at 232.* The study noted that causes of band erosion are not known but "could be related to ischemia of the gastric wall caused by a tight ring… over filling of the chamber… or infection…" *Id. at 232.*

The study noted that other studies have indicated, similar to the present study, that this incident of band migration may have previously been under-reported because band erosion increases over time "because migration occur a long time after band placement". *Id. at 233.*

The study authors concluded that "only long-term" endoscopic follow-up will confirm the true incidence of prosthesis migration in banded patients [and that]

"[g]uidelines for the management of band erosion are strongly recommended." *Id. at 233.*

50. In 2003, a study was published that showed that 50% of patients that had the Lap-Band® implanted at the Medical College of Virginia, had to have their Lap-Band® surgically removed within forty-two (42) months. DeMaria, E, *Laparoscopic Adjustable Silicone Gastric Bonding: Complications.* J. Laparoendosc Adv. Surg. Tech 2003; 13(4) 271-277. Moreover, 71% of patients who underwent both preoperative and postoperative contrast studies showed a postoperative esophageal diameter that was on average 182% of the baseline diameter during an average of 21 months, "the mean preoperation esophageal diameter was 2.2 cm, which increased to 3.3 cm postoperatively". Moreover, 12 of 17 patients with severe dilation were symptomatic with dysphagia (difficulty swallowing), vomiting or severe reflux. The study also stated the "[w]orsening esophageal dilation and inadequate weight loss mandate conversion to an alternative bariatric procedure". This article goes on to note that:

> We believe that all [Lap-Band®] patients should undergo routine contrast studies at 4 years after devices insertions. Management of the progressively dilating esophagus should include deflation of the device, despite the fact that weight gain is likely. Failure of the esophageal contour to return to normal should probably be treated by band removal. We have found most of our patients to be significantly concerned about the possible long-term health effects of esophageal dilation.... We advise such patients to undergo conversion to gastric bypass.
>
> The study concludes:
> More study is needed to determine the long-term efficacy of the [Lap-Band®] procedure, but it is difficult to comprehend why an operation after which 30% of patients fail to lose at least 30% of their excess weight would be judged beneficial. Finally, given the significant long-term risk for failure and the observation that

> revision of [the Lap-Band®] to an alternative bariatric procedure (e.g. gastric bypass) carries a higher risk then does a primary gastric bypass procedure, one must question the role of the [the Lap-Band®] in bariatric surgery treatment today.
> *Id. at 276.*

51. Another study was published in 2003 which compared the Lap-Band® System to laparoscopic vertical banded gastroplasty ("LVGB") for the treatment of morbidly obese patients. Morino, M., Toppino, M., Bonnet, G., et al. *Laparoscopic Adjustable Silicone Gastric Banding verses Vertical Banded Gastroplasty in Morbidly Obese Patients*; Annals of Surg., 2003; 6. Vol 238:835-842. The study found the LVGB was superior to the Lap-Band® concerning producing higher weight loss, fewer long-term complications and fewer reoperations. Specifically, the study found that the late complications rates for LVGB was 14% for the LVGB versus 32.7% for the Lap-Band®; the reoperative rate was 0% for the LVGB verses a reoperation rate for the Lap-Band® of 24.5% and that weight loss for the LVGB was 63.5% at 2 years and 58.9% at 3 years verses the Lap-Band® which had a weight loss at 2 years of 41.4% and 39% at 3 years. The authors of the study concluded that their study:

> confirms concerns of some authors regarding the uncontrolled spread of the [Lap-Band®] without verification of the long-term outcomes…Following the release of the data summarized in this article, we have decided to suspend the routine clinical application of the [Lap-Band®].
>
> *Id. at 840.*

52. Another study, published in 2005, examined the prevalence and significance of band erosion after the Lap-Band® procedure. Hainaux, B., Agneessens, E., et al. *Intragastric Band*

Erosion After Laparoscopic Adjustable Gastric Banding for Morbid Obesity: Characteristics of an Underreported Complication. AJR; 2005; Jan;109-112. The study notes that band erosion involves the silicone ring penetrating the gastric wall, and in some patients the lumen of the stomach. "It typically is a late stage complication caused by chronic ischemia due to pressure applied to the gastric wall." *Id. at 110.* The study notes that "the reported prevalence of band erosion varies from none to up to 11%". *Id.* The study concludes that these variations could be due to differences in the length of follow-up of the study and the type of routine studies performed during follow-up. The study notes that in a series of 119 patients reported by Silecchia, et al. with minimum follow-up period of 12 months (mean follow-up 32 months), the rate of band erosion was 7.5% because all patients, even if asymptomatic, underwent routine gastrointestinal endoscopy. The study goes to note that all of the patients in the Silecchia, et al., study were asymptomatic at the time of their band erosion diagnosis. The study concludes:

> In conclusion, intragastric band erosion is a major complication of laparoscopic adjustable gastric banding, often leading to additional surgery. The prevalence of this complication will probably increase over time because patients may remain asymptomatic for long periods and because band erosion occurs long after band placement. Radiologists in charge of postoperative evaluation of patients after bariatric surgery should be aware of the characteristic imaging finding of this underreported complication to detect it at the earliest possible stage.
>
> *Id. at 110.*

53. Another study published in 2004, compared the Lap-Band® to gastric bypass and concluded that gastric bypass was superior to the Lap-Band® System. Weber, M., Muller, M., et al., *Laparoscopic Gastric Bypass is Superior to Laparoscopic Gastric Banding for Treatment of Morbid Obesity*, Annals of Surg., 2004;6:975-982. Gastric bypass was found to be superior

to the Lap-Band® System in late complications, weight loss and the reduction of comorbidities like diabetes, hypertension and dyslipidemia.

The study notes that the Lap-Band® has shown a "high incidence of long-term failures and complications. For example, band erosion, band slippage, and esophageal dilation occur between 15% and 58% of the cases". *Id. at 976.* The study concludes as follows:

> The higher incidence of early complications in the gastric bypass group is outweighed by a significantly higher rate of late complications in the [Lap-Band®] group. The [Lap-Band®] procedure is associated with a higher rate of reoperations requiring eventually a conversion to a bypass procedure in many patients. Moreover, laparoscopic gastric bypass offers a significant advantage regarding weight loss and reduction in comorbidities after surgery. Therefore, in our hands, laparoscopic Roux-en-Y gastric bypass is superior to [the Lap-Band® System].
> *Id. at 981.*

54. In 2004, another study was published which studied a group of patients that had the Lap-Band® System implanted between March 1993 and June 1999. The patients were followed for up to 9 years, with an average follow-up period of 55 months. Martikainen, T., Pirinen, E., et al., *Long-term Results, Late Complications and Quality of Life in a Series of Adjustable Gastric Banding*. Obes. Surg. 204; 14;648-654.

During the follow-up period, 54% of patients experienced postoperative complications that required hospital treatment of greater than or equal to 7 days, 52% underwent a reoperation and 33% of the Lap-Bands® were removed. The most important late complications were band erosion (9%), esophagitis (30%), obstruction due to slippage/pouch dilation (21%), and incisional hernia (9%).

Changes in excess weight loss, obesity-related co-morbidities, and quality of life (QOL) were also assessed in the study in accordance with the Bariatric Analysis and Reporting Outcome System ("BAROS"). According to BAROS, use of the Lap-Band® was regarded as a failure

in 50% of the patients, fair in 40% of the patients, good in 7% of the patients and very good in 3% of the patients. *Id. at 648.*

The study notes that "[w]ith respect to major complications, band erosion occurred in 9% of the patients". *Id. at 651.* The study went on to note:

> Band erosion is a serious complication after gastric banding and required band removal... In our study, the number of erosions [9%] was comparable to most previous studies. ...Because of the high rate of erosion, all patients need to be followed with annual gastroscopic, which add substantial cost to the procedure in the long term.
>
> *Id. at 653.*

55. In another study, also published in 2004, a group of patients had the Lap-Band® implanted between 1990 and 1996 and were followed over an average of 105 months (range 72-151 months). Camerini, G., Gianfranco, A., *Thirteen Years of Follow-up in Patients With Adjustable Silicone Gastric Banding for Obesity: Weight Loss and Constant Rate of Late Specific Complications.* Obes. Surg. 2004;14:1343-1348. The study concluded that while the Lap-Band® System "yielded good short-term results, ... the progressive weight regain and constant risk of complications in the long-term tend to nullify the optimism". *Id. at 1343.* The study notes that the authors encountered both short and long-term complication "which required reoperative surgery in more than two-thirds of the patients and devices removal in more than one-half." *Id. at 1343-1344.* The study also noted that "[e]xcluding four early events occurring within the first 8 months after operations, the cumulative risk of band removal increased linearly with time... [with] removal ...expected in about 1 out of 10 patients every year". *Id. at 135, 1346.*

The study went on to note that because the Lap-Band® System was the "least invasive procedure it is easy for a surgeon to get involved with a large series before realizing what the incidence of complication is." *Id. at 1348.* Because of this the Lap-Band® System "was used greatly in Europe, and became by far the most performed procedure before the first alarming signals appears." *Id. at 1348.* The study concludes:

> The aim of this paper, based on the longest existing follow-up **is to provide a warning.** The surgeon who adopts the [Lap-Band®] operation, encouraged by the good short-term results, can potentially carry out a great number of these operations in a short period of time. Should the long-term outcome be similar to ours, this discovery would be more costly with a larger series than with a small one. ***(emphasis added)***
>
> *Id. at 1348.*

56. Another study, published in 2006 conclude that "[w]ith a 40% 5 year failure rate and a 43% 7-year success rate, [the Lap-Band®] should no longer be considered the procedure of choice for obesity." Suter, M., Calmes, J.M., et al,. *A 10-year Experience with Laparoscopic Gastric Banding for Morbid Obesity; High Long-term Complications and Failure Rates.* Obes. Surg. 2006;16:829-835.

The study defined major complications "as those requiring band removal (major reoperation), with or without conversion to another procedure." *Id. at 829.*

The study found that 33.1% of the patients developed late complications, including band erosion in 9.5% of patients, and that major reoperations were required in 21.7% of patients. *Id. at 829.* The study also found that each year contributes 3-4% to the major complication rate, which contributes to the total failure rate. *Id. at 829.*

The study discussed the high incidence of band erosion (9.5%) that it found, in pertinent part, as follows:

> Two groups looking specifically for [band erosion] using routine endoscopy, also found a high incidence of erosions. As band erosion is often asymptomatic, or only associated with slight abdominal discomfort and/or weight regain, and since endoscopy is not performed routinely, it can be assumed that the true incidence of band erosion is underestimated in the literature. **This is a major concern to us, because band erosion represents a total failure of the concept of gastric banding.** Furthermore, it is associated with dense scarring and distortion of the tissue at the level of the cardia, which can seriously complicate re-do surgery, even if it is performed openly. ***(emphasis added)***
>
> *Id. at 834.*

The study also notes that a considerable amount of time is needed "to apprehend the high incidence of the long-term complications after [implanting the Lap-Band® System]." *Id. at 834.* "The formidable enthusiasm that embraced many surgeons during the late 1990's is now fading away at least in Switzerland and Europe". *Id. at 834.* The study goes on to warn:

> Laparoscopic gastric banding was introduced in the USA only a few years ago. As in Europe, and before the appearance of long-term complications, the enthusiasm related to the apparent simplicity of the procedure and good early results might drive a considerable number of surgeons and patients to choose gastric banding for morbid obesity. If long-term results mimic those reported in this paper, **this could cause a disaster, with thousands of patients requiring reoperations, with-their associated risks,** because of severe long-term complications and/or insufficient [lost] weight. The results presented in this paper should serve as a warning.
>
> *Id. at 834*

57. A study published in 2005 compared gastric bypass to use of the Lap-Band® as a weight loss method for super obese patients. Mognol, P. , Chosidow, D., et al., *Laparoscopic Gastric Bypass versus Laparoscopic Adjustable Gastric Banding in the Super-Obese: A Comparative Study of 290 Patients*. Obes. Surg. 2005;15:76-81. The study took place between 1994 and 2004. *Id. at 76.* During this time period the Lap-Band® procedure was the study groups

primary bariatric procedure. As a result of the study outcome, the physicians involved in the study groups changed to primarily using a gastric bypass with their super-obese patients. This decision was the result of gastric bypass having significantly better excess weight loss than the Lap-Band® system, patients implanted with the Lap-Band® System has greater "gastrointestinal symptoms, because patients are unable to eat regular food and the incidence of vomiting is high." *Id. at 80.* Moreover, "[p]atients with [gastric bypass] have a significantly better quality of life than patients who underwent a restrictive operation". *Id. at 80.* The authors also noted that while they had used gastric bypass as a revision procedure after a failed Lap-Band®, revision surgery is "often associated with increased morbidity, which is why we prefer to perform [gastric bypass] as a primary operation in super-obese patients." *Id. at 80.*

58. Another study, published in 2006, compared the effectiveness and safety of using gastric bypass verses the Lap-Band®. Brown, W., Jilliard, K., et al., *Laparoscopic Gastric Bypass is Superior to Adjustable Gastric Band in Super Morbidly Obese Patients.* Arch. Surg. 2006;141:683-689. The study concluded that gastric bypass was more effective at achieving weight loss and reducing co-morbidities than the Lap-Band® and that the Lap-Band® was less safe than gastric bypass producing a greater incidence of late complications and reoperations.

59. A study published in 2008 seems to directly address, and refute the Lap-Band® Defendants' claims that as the Lap-Band® System is just as effective but safer than gastric bypass. Till, J., Karliner, L., et al. *Gastric Banding or Bypass? A Systematic Review Comparing the Two Most Popular Bariatric Procedures.* Am. J. Med 2008; 121:885-893.

The study authors conducted a comprehensive search of medical study databases such as MEDLINE, Cochrane Clinical Trials and others looking for studies that compared laparoscopic adjustable gastric banding with Roux-en-Y gastric bypass. After reviewing the studies comparing these two procedures, the authors conclude that "[w]eight loss outcome strongly favored… [gastric bypass] over laparoscopic adjustable gastric banding," *Id. at 885.* Moreover, the authors conclude that "[g]astric bypass should remain the primary bariatric procedure used to treat obesity in the United States." *Id. at 885.*

The study goes that "[l]aparoscopic adjustable gastric banding is marketed as a less-invasive, potentially reversible alternative to Roux-en-Y gastric bypass, because the procedure does not require gastrointestinal bypass and reanastomosis." *Id. at 886.* The study authors go on to note that "[t]here is a risk that commercial sponsorship of laparoscopic adjustable gastric banding may promote the use of these devices over Roux-en-Y gastric bypass, which has no commercial sponsor." *Id. at 89.*

The study authors note that "Roux-en-Y gastric bypass is currently the standard bariatric procedure in the United States." *Id. at 886.* The study authors go onto note that "[g]iven the rapid increase in bariatric procedures in the United Sates, it is important for internists to understand the relative strengths and weakness of each procedure such that patients and their doctors can make informed, evidenced based decisions.". *Id. at 886.* "The present systematic review of all studies directly comparing Roux-en-Y gastric bypass with laparoscopic adjustable gastric banding was conducted with the aim of evaluating the relative safety and efficiency of the 2 procedures." The study showed that "[w]eight loss outcome consistently favored Roux-en-Y gastric bypass by a substantial margin." *Id. at 888.* The study goes on to state that "[t]hese results were mirrored in the data for the resolution of comorbidities." *Id. at*

888. "The results of the 2 studies that matched patients strongly favored the Roux-en-Y gastric bypass group, with absolute difference in the resolution of comorbidities of 25% or more...."

The study also found that long-term complication rates and long-term reoperative rates also favored Roux-en-Y gastric bypass over use of the Lap-Band®. *Id. at 889.*

The study concludes: "[u]ntil trials demonstrate the advantage of laparoscopic adjustable gastric banding in clearly defined subgroups of patients, Roux-en-Y gastric bypass should remain the bariatric procedure of choice in the United States". *Id. At 892.*

60. In a letter to the Annals of the Royal College of Surgeons of England in 2008, Dr. Jacques M. Himpens discussed his view concerning gastric bypass verses adjustable gastric banding for the treatment of morbid obesity. Himpens, J. *Gastric Banding, - - To Band or Bypass.* Ann R. Coll. Surg. Eng. 2008;90:2-6. Himpens notes that with adjustable gastric banding, "[r]e-operation rates continue to rise after 10 years or more." *Id. at 3.* Himpens goes on to note that "[m]any [Lap-Band®] patients will need another bariatric operation at some point in the future, be it for obesity recidivism or for adverse effects of the technique." *Id. at 3.* Moreover, "[t]here is substantial evidence that re-do operations are technically more demanding, more prone to complications, and less effective than primary ones." *Id. at 3.* The note concludes as follows:

> Adjustable band gastroplasty in the treatment of obesity appears to be operator (or county) dependent. The excellent results obtained by some are in sharp contrast to the experience of most others. A good procedure should be easily replicable, not only considering the technique itself, but also considering the approach to follow-up. As long as this is not the case, the adjustable band will remain a questionable tool for many bariatric surgeons, including ourselves.

Id. at 3.

61. In a study, published in 2009, the safety and effectiveness of the gastric bypass, and adjustable gastric banding were compared. Gutter, U., Lazar, K. et al. *Safety And Effectiveness Of Bariatric Surgery: Roux-en-Y Gastric Bypass Is Superior To Gastric Banding In The Management Of Morbidly Obese Patients.* Patient safety in surgery, 2009, 3:10

The study searched online databases such as PubMed, Cochrane library and others along with manually searching references from systematic reviews for articles not otherwise identified along with contacting several experts in the field to identify important unpublished data for medical article/studies converge, concerning adjustable laparoscopic banding and Roux-en-Y gastric bypass for morbid obesity published up through March 31, 2009. *Id.*

After analyzing the results of the research noted above, the authors conclude that there are numerous studies "that report rates of gastric band removal up to 60%". *Id.* The study goes on to note that "[t]he rapidly increasing body of scientific evidence on high rates of re-operation after gastric banding is alarming." *Id.* The study concludes that "[t]here is mounting and convincing evidence that laparoscopic adjustable gastric bandage is suboptimal at best in the management of morbid obesity. Although short to term morbidity is low and hospital length of stay is short, the rates of long-term complications and band removals are high, and failure to lose weight after the laparoscopic gastric banding is prevalent." *Id. at 1 of 4.* The study goes on to conclude that "[t]he placement of a gastric band appears to be a disservice to many morbidly obese patients and therefore, in the current culture of evidence based medicine, the prevalent use of laparoscopic gastric bandage can no longer be justified." *Id. at 1 of 4.* The study goes on to conclude that "[b]ased on the current scientific literature,

the laparoscopic gastric bypass should be considered the treatment of choice in the management of morbidly obese patients". *Id. at 1 of 4.*

62. In 2011, a study was published which studied the long-term efficiency and safety of the Lap-band system as a treatment for morbid obesity. Himpens, J. et al. *Long-term Outcomes of Laparoscopic Adjustable Gastric Bandages*. Arch. Surg. 2011; 146; 802-807

The study found that 28% of Lap-Band® system patients experienced band erosion, 39% experience major complications (including 28% with band erosion), nearly 50% required removal of the bands (contributing to a reoperation rate of 60%), and 17% of the patients had their procedure switched to laparoscopic Roux-en-Y gastric bypass. *Id. at 801.*

Concerning the 28% of patients that experienced band erosion, the average time to diagnosis of band erosion was 4 years (range, 1-11 years). Regarding the high number of band erosions, the study authors stated "[t]heoretically, it is not surprising that a rigid structure placed around a hollow organ would erode in the lumen of the latter, as experienced earlier with the Angelchik prosthesis (a prosthesis ring wrapped around the esophagus for the surgical treatment of gastroesophageal reflex disease – high complication rates led to disuse)." *Id at 804.*

The study authors conclude "[t]he high failure rate of [the Lap-Band® system], at least in our hands, could be detrimental to its future continued widespread use as a restrictive weight loss operation". *Id at 804.*

63. A study published in 2013 looked at gastric bypass as a rescue procedure after failure of the Lap-Band®. Worni, M., Ostbye, T. et al. *High Risks For Adverse Outcomes After Gastric Bypass Surgery Following Failed Gastric Banding*, Ann Surg 2013; 257: 279-285.

The study notes that "numerous single-center series indicate that revision may be necessary for 12% to 60% of patients" and that "[i]f major complications or excessive weight gain occur after a gastric banding procedure, a revisional procedure is often performed." *Id at 279.* This study sought to compare the outcome for patient undergoing primary gastric-bypass surgery with these who had gastric bypass procedures performed as a rescue procedure for complication of gastric banding. *Id at 279.*

The study used the Nationwide Inpatient Sample, a Healthcare cost and utilization project for their data analysis from 2005 to 2008. *Id at 279.* The Nationwide Inpatient Sample is a prospectively collected national administrative database. It represents about 1000 community hospitals in the United States that are open throughout the year. *Id at 279.*

The study notes that between 2005 and 2008, the number of band related reoperations increased from 579 in 2005 to 1132 in 2008, a 196% increase. *Id at 282.* Moreover, band related reoperations concomitant with a rescue bariatric procedure (rescue gastric bypass operations increased 160% alone) increase 221% per year. *Id. at 282.*

The study found that patients undergoing a gastric bypass procedure after failed gastric banding have worse outcomes than those undergoing primary gastric bypass. *Id. at 282-283.* As noted by the study "there were significantly more intraoperative and postoperative complications, higher rate of postoperative reoperations/reoperations, longer hospital stays, and higher total hospital charges." *Id. at 283.* The study also points out that other studies have found that it "adhesions to the stomach, liver, and parietal peritoneum and thick scar tissue around the band were present in all [former Lap-Band®] patients." *Id. at 283.*

The study authors were concerned because of the dramatic 300% increase in Lap-Band® procedures from 2004 to 2007 in the United States, the up to 60% Lap-Band® failure rate

and need for a band related reoperation, and the significant difficulty and complication rate associated with a rescue bariatric procedure. *Id. at 283-284.* The study concludes:

> In summary, the number of patients undergoing a reoperation after gastric banding dramatically increased from 2005 to 2008. Analysis of outcomes comparing patients undergoing gastric bypass surgery after earlier gastric band operation with patients undergoing primary gastric bypass clearly favors primary gastric bypass procedures. In fact, gastric bypass procedure after failed gastric banding is associated with significantly more intra- and post operation morbidity, higher rate of reoperations, a significantly longer hospital stay and higher hospital charges. The broad indication for gastric banding should be reaffirmed for the US population.
> *Id. at 284.*

64. A study, published in 2017 looked at the long-term effectiveness and safety of the Lap-Band® noting "the effectiveness of a bariatric procedure is mainly measured by the maintenance of long-term results." Carandina, S., Tabbara, M., et al. *Long-Term Outcomes Of The Laparoscopic Adjustable Gastric Banding; Weight Loss And Removal Rate: A Single Center Experience On 301 Patients With A Minimum Follow-Up Of 10 Years.* Obes. Surg. 2017 Apr; 27(4): 889-895.

The study found that only 50.1% of Lap-Band® were still implanted in their facilities' patients after 15 years. *Id at 892.* Moreover, revisional surgery was performed in 56.3% of patients who had their band removed. *Id at 892.* "A total of 256 reoperations were performed in 180 patients (59.8%). Seventy-six patients (25.2%) needed at least two reoperations." *Id at 892.* The study authors stated:

> If we take into account the number of reoperations, including conversion to other bariatric procedures and restoration of port site complications, almost 60% of patients experienced at least one

> reoperation. This risk must be communicated to the patient when proposing a [Lap-Band®].
>
> *Id at 894.*

The study concludes as follows:

> In 2006, Suter et al. warned the scientific community that if early results reported in their study were confirmed in the long-term, thousands of patients would require reoperations because of severe complications and/or insufficient weight loss. Ten years later, our results confirm their prediction: [the Lap-Band®] achieves an effective long-term weight loss in no more than 20% of patients and is associated with a significant reoperation rate. Its durability is compromised by the associated complications and its removal rate increases at 3-4% per year, with almost half of the bands removed at 15 years. The results help to understand the dramatic decrease in [Lap-Band®] procedures worldwide.
> *Id at 895*

65. Another study, also published in 2017, found similar long-term failure rates with the Lap-Band®. Vinzens, F., Kilchenmann, A., et al. *Long-Term Outcome Of Laparoscopic Adjustable Gastric Banding (LAGB)*: results of a Swiss single-center study of 405 patients with up to 18 years follow-up. Surg. Obes. Relat. Dis. 2017 Aug; 13(8): 1313-1319

The study starts off documenting the rise of the Lap-Band® procedure starting in 1993 in Europe and Australia, its traveling to the USA until 2007 when "the frequency of [Lap-Band®] in bariatric surgery [was]… up to 100,000 procedures a year". *Id at 1313.* The study also notes that as of 2017, the procedure has been almost abandoned in both Europe and the United States due to increasing band-associated complications and the emergence of more popular procedures such as a Roux-en-Y gastric bypass. *Id at 1313.*

The study followed 405 patients treated with the Lap-Band® between 1996 and 2010 at the authors' institution with a minimum follow-up of 10 years and maximum follow-up of 18 years. *Id at 1315.*

The study found that 63% of the authors' patients underwent revisional bariatric procedures due to complications, insufficient weight loss, or secondary weight regain. *Id at 1315.* Additionally, "port-tubing revisions were performed 45 times in 38 patients leading to an overall reoperation rate of 78%." *Id at 1315.* Finally, at the end of the study's follow-up, "only 29% had a band in place and just 15% reached a good to excellent result… [L]ong-term follow-up revealed a worryingly high reoperation rate of 78%". *Id at 1316-1317.*

The study also noted that "Favretzi, et al., describe reversibility as being the one of the most favorable characterization of the gastric band. Our analysis of patients with definitive band removal does not corroborate this statement. On the contrary, 23%... of the patients undergoing band removal without subsequential revisional bariatric procedure still suffered from food intolerance 5±4 years after band removal." *Id at 1318.* The study reached the following conclusion:

> [Lap-Band®] is a weight-loss effective but nonreversible [procedure], and carries a high complication rate leading to reoperation. Symptoms can persist even after removal for up to 23% of patients. "**Gastric banding should not be the treatment of choice for patients with refractory obesity after failed conservation management.**" ***(emphasis added)***
> *Id at 1318*

66. In 2012, after issues surrounding the advertising and marketing of The Lap-Band® in southern California, members of the United States Congress called for an investigation of the safety and effectiveness of the Lap-Band® device.

67. The most recent labeling reports the results from the pivotal study and the "Lower BMI Study" that was used to support the labeling change allowing use in patients with BMI as low as 30. Those results show that in the pivotal study, over three years, approximately 25% of the 299 study participants had their device removed. Approximately 17% of the 299 had the device removed as a counter measure to an adverse event. Approximately 1.3% had the device removed due to erosion.

68. In the Lower BMI study, the labeling reports that over one year, 1 out of 149, or 0.7% of patients, suffered erosion. This patient, along with two others, or 2%, suffered a serious adverse event requiring band removal.

69. A review of the entries in the FDA's MAUDE (Manufacturer and User Facility Device Experience) database of adverse events reveals hundreds of instances of the Lap-Band® causing erosion. The database contains a "manufacturer's narrative" in response to each of the hundreds of complaint entries. The response to a report about erosion often contains language such as the following:

> GASTRIC EROSION IS A SURGICAL/PHYSIOLOGICAL COMPLICATION AND ANALYSIS OF THE DEVICE GENERALLY DOES NOT ASSIST ALLERGAN IN DETERMINING A PROBABLE CAUSE FOR THESE EVENTS... DEVICE LABELING ADDRESSES THE POSSIBLE OUTCOME OF EROSION AS FOLLOWS.... "THERE IS A RISK OF BAND EROSION INTO STOMACH TISSUE..."

70. According to Allergan, 750,000 procedures have been performed between 1994 and 2013. In 2013 alone, there were 25,000 gastric band implantation surgeries. There were 358 adverse event reports (filed between 2013 and 2015) in the MAUDE database regarding events that took place in 2013, that mentioned erosion. Assuming that all 25,000 were The Lap-Band®s (and not Realize, the other adjustable gastric band on the market), that is a 1.4% rate of reported erosion events (in the same year as implantation). That matches the manufacturer's estimate derived from the pivotal study almost exactly.

71. The failure rate the Lap-Band® defendants reported in the MAUDE database is directly contradicted, however, by numerous medical studies which show that the number of patients whose Lap-Band® eventually erodes into the stomach is between 3% and 28% or higher. *See, e.g.*, the medical studies discussed herein and Jacques Himpens et al, *Long-term Outcomes of Laparoscopic Adjustable Gastric Banding*, 146 ARCH. SURG. 802 (2011) (following up on

patients who had received their The Lap-Band® between 1994 and 1997 in Europe prior to FDA approval, with a median follow-up time of 13 years, finding nearly 50% required removal and nearly 1 in 3 experienced erosion).

72. Lap-Band® Defendants have executed a plan to cash in on the Lap-Band® at the expense of patient safety despite repeated warning from the medical community that the Lap-Band® had a high long-term serious complication rate including band erosion, a high re-operation rate and a high rate of surgical band removal - - causing many in the medical community to issue warnings that the Lap-Band® should not be used, that use of the Lap-Band® would be costly to patients, that the Lap-Band® erosion "represents a total failure of the concept of gastric banding;," that thousands of patients would need reoperations if they used the Lap-Band®, that the Lap-Band® was not as effective as gastric bypass and eventually leading to the majority of bariatric surgeons worldwide abandoning the use of the Lap-Band® as a weight loss procedure.

But bariatric surgeons abandoning the Lap-Band® happened despite the best efforts to market the Lap-Band® device by the Lap-Band® Defendants. And it did not occur until after thousands of patients, including Plaintiffs, underwent the Lap-Band® procedure and suffered the severe complications that the Lap-Band® Defendants' knew about and attempted to cover-up for over a decade. In fact, as described herein, not only did the Lap-Band® Defendants not report the information about the high long-term complication and failure rate of the Lap-Band® device, the Lap-Band® Defendant aggressively marketed the Lap-Band® device through T.V., internet, seminars, videos and a trained marketing sales force including bringing in an outside company, Covedian, to market the Lap-Band® to the bariatric surgeon community.

In their T.V., internet, seminars, video, brochure and sales force marketing, the Lap-Band® Defendants' claim that the Lap-Band® was "safe but just as effective as gastric bypass", that that it was "up to 10 times safer than gastric bypass", that the Lap-Band® procedure is the "[o]nly surgical option designed to maintain long-term weight loss", and that the Lap-Band® has "fewer risk and side effects", than gastric bypass. None of these statements were approved by the FDA nor were they part of any FDA approved labeling. Most, importantly, all of these statements are demonstrably false, and were prohibited by both the FDA PMA, federal law and parallel Missouri law.

The Lap-Band® Defendants also failed to warn the FDA and failed to submit a PMA supplement, when the Lap-Band® Defendants knew, or should have known, that this rate of Lap-Band® erosion was higher than 1%. The Lap-Band® Defendants were required to warn the FDA under the PMA approval letter, federal law and parallel Missouri law. The Lap-Band® Defendants' also falsely stated the Lap-Band® erosion only required "minor revisonal surgery" when, in fact, Lap-Band® erosion is describe in the FDA approved Lap-Band® warning label as a "serious adverse event", that "[r]e-operation to remove the device is required" with band erosion, that "[r]e-operation for band erosion may result in gastronomy" - - that is surgical removal of part of all of the stomach. Moreover, as noted herein, bariatric surgeons consider band erosion as potentially life threating and a total failure of the concept of the adjustable gastric band.

As a result of the Lap-Band® Defendants both failing to warn of the true incidence of Lap-Band® erosion, failing to submit a PMA supplement warning of the true incident of Lap-Band® erosion and lying about the life-threating nature of band erosion, thousands of patients

underwent the Lap-Band® procedure, and thousands of patients suffered band erosion including Plaintiffs.

73. Lap-Band® Defendants had the duty to monitor the medical studies conducted concerning gastric bands. However, they carefully managed their MAUDE submissions to ensure that the failure rate matched the failure rate it had previously reported to the FDA. The studies themselves that the Lap-Band® Defendants were using as a basis for their MAUDE reports found much higher rates of erosion, particularly at follow-up years after implantation. This is prima facie evidence that Lap-Band® Defendants were violating Federal and parallel Missouri law by underreporting adverse events, in a deliberate attempt to avoid having to update their label to reflect the true risks—and to avoid making clear to patients that they would most likely need to have the device removed because of an adverse event including stomach erosion.

74. If Lap-Band® Defendants complied with federal law, the high band erosion, re-operation and band removal rates would have been known to the FDA, Plaintiffs, Plaintiffs' physicians and to the public. Under its PMA, the Lap-Band® defendants were required to submit a new warning label when it had information indicating adverse events were worse than had been reported to the FDA. Moreover, the public would have known of the significant risk of adverse events whether or not the FDA mandated labeling changes, because the MAUDE database is publicly available, and physicians and the media look at the MAUDE database. Finally, if the FDA had been notified of the true, significantly high rate of stomach erosion and subsequent need for removal, it is more likely than not that the FDA would have changed the label.

IV. Lap-Band® Representations

75. At all relevant times, The Lap-Band® was researched, developed, manufactured, marketed, advertised, promoted, sold and distributed as a safe and effective device to be used for weight loss.

76. The Lap-Band® Defendants knew, and/or had reason to know, that the Lap-Band® was defective, unreasonably dangerous and not safe because of the high number of adverse events that both companies knew about.

77. Defendants negligently, carelessly, recklessly, and/or intentionally promoted the Lap-Band® to physicians and patients, including the Plaintiffs and Plaintiffs' physicians.

78. The Lap-Band® Defendants downplayed to physicians and patients, including Plaintiffs and Plaintiffs' physicians, the dangerous complications of long-term use of the Lap-Band®.

79. The Lap-Band® Defendants misrepresented the safety of the Lap-Band® to physicians and patients, including Plaintiffs and Plaintiffs' physicians.

80. The Lap-Band® Defendants willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiffs and Plaintiffs' physicians, of the increased risks and significant dangers resulting from being implanted with the Lap-Band® device.

81. The Lap-Band® Defendants knew and/or had reason to know, that their representations and suggestions to physicians that the Lap-Band® was safe and more effective than alternative weight loss methods were materially false and misleading such that physicians and patients, including Plaintiffs and Plaintiffs' physicians, would rely on such representations.

82. The Lap-Band® Defendants knew or should have known and/or recklessly disregarded the materially incomplete, false and misleading nature of the information that they caused to be

disseminated to the public and to physicians, including Plaintiffs and Plaintiffs' physicians, as part of their campaign to promote the Lap-Band®.

83. Any warnings The Lap-Band® Defendants may have issued concerning the risks and dangers of the Lap-Band® were inadequate and insufficient in light of their contradictory prior, contemporaneous and continuing illegal promotional efforts of the Lap-Band® to hide or downplay the true risks and serious dangers of the device.

84. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest levels of the Lap-Band® Defendants, including the corporate officers and directors.

85. The Lap-Band® Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the promotion, sale, and distribution of the Lap-Band®, but they concealed this information and did not warn the FDA, Plaintiff or Plaintiff' physicians, preventing Plaintiff and Plaintiff' physicians from making informed choices in selecting alternative weight loss procedures prior to Plaintiff' the Lap-Band® implantation procedure and preventing Plaintiffs and Plaintiffs' physicians from timely discovering Plaintiffs' injuries.

86. Plaintiffs would not have consented to undergo the Lap-Band® or would have had the Lap-Band® device removed prior to injury had Plaintiffs known of or been fully and adequately informed by the Lap-Band® Defendants of the true increased risks, hazards, and serious dangers of the Lap-Band®.

87. Plaintiffs reasonably relied on the Lap-Band® Defendants' representations and omissions regarding the safety and efficacy of the Lap-Band®.

88. Plaintiffs did not know of the specific increased risks and serious dangers, and/or were misled by the Lap-Band® Defendants, who knew or should have known of the true risks and dangers,

but consciously chose not to inform Plaintiffs or their physicians of those risks and to actively misrepresent those risks and dangers to the Plaintiffs and Plaintiffs' physicians. The Lap-Band® Defendants' promotion and marketing of the Lap-Band® caused Plaintiffs' physicians to decide to recommend and implant the Lap-Band® in Plaintiffs. Plaintiffs' physicians would not have recommended and performed the Lap-Band® procedure in the absence of Defendants' false and misleading promotion. Additionally, the Lap-Band® Defendants direct marketing to Plaintiffs through brochures, T.V., the internet, seminars, and videos misled Plaintiffs and caused them to undergo the Lap-Band® procedure.

V. Damages Caused by Lap-Band®

89. Plaintiffs have suffered serious personal injuries as a direct and proximate result of Lap-Band® Defendants' illegal misconduct.

90. As a direct and proximate result of Lap-Band® Defendants' illegal conduct, Plaintiffs have suffered and will continue to suffer from severe injuries and damages

91. As a result of Lap-Band® Defendants' scheme to falsely promote the Lap-Band® and their failure to warn of the risks, dangers and adverse events associated with the Lap-Band® as manufactured, promoted, sold and supplied by Lap-Band® Defendants, and as a result of the negligence, callousness, and other wrongdoing and misconduct of Lap-Band® Defendants as described herein:

A. Plaintiffs have been injured and suffered and will continue to suffer injuries to their bodies, The exact nature of which are not completely known to date;

B. Plaintiffs have sustained and will continue to sustain economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

C. Plaintiffs have incurred and will be required to incur additional medical expenses in the future to care for themselves as a result of the injuries and damages Plaintiffs have suffered;

D. Plaintiffs are therefore entitled to compensation damages in an amount to be proven at trial, and punitive damages together with interest thereon and costs.

VI. Lap-Band® Defendants Agency, Alter-Ego, Joint Venture, and Conspiracy

92. At all times herein mentioned, Lap-Band® Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of the Lap-Band® Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and Lap-Band® Defendants and each of them thereby ratified those actions.

93. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Lap-Band® Defendants and other certain Lap-Band® Defendants such that any individuality and separateness between the certain Lap-Band® Defendants has ceased, and these Lap-Band® Defendants are the alter-egos of the other certain Lap-Band® Defendants and exerted control over those Defendants.

94. Each of the Lap-Band® Defendants herein expressly or impliedly agreed to work with and assist each other, Lap-Band® Defendants, and unnamed parties, toward the common purpose of promoting, recommending and selling the Lap-Band® and toward the common interest of pecuniary gain.

95. Each of the Lap-Band® Defendants herein performed the acts and omissions described herein in concert with the other Defendants herein and/or pursuant to a common design with the other Defendants herein.

96. Each of the Lap-Band® Defendants herein knew the acts and omissions of the other Defendants herein constituted a breach of duty, and yet, each Lap-Band® Defendant herein provided each other Lap-Band® Defendant substantial assistance and/or encouragement.

97. Each of the Lap-Band® Defendants herein provided substantial assistance to the other Defendants herein in accomplishing the intentional and tortious conduct described herein, and each of the Lap-Band® Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

98. At all times herein mentioned, each of the Lap-Band® Defendants were engaged in the business of and/or were a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling the Lap-Band® device for use by the Plaintiffs and the Plaintiffs' physicians. As such, each of the Lap-Band® Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

99. The conduct of the Defendants herein caused the Plaintiffs' harm as described herein. The Plaintiffs' harms is not in any way attributable to any fault of the Plaintiffs. Uncertainty may exist regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' harm. The Defendants possess superior knowledge and information regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' injuries. Thus, the burden of proof is upon each Defendant to prove the Defendant did not cause the Plaintiffs' harm as described herein.

100. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

101. Due to the above, each Cause of Action named below is asserted against each Defendant herein, jointly and severally, even if each and every Defendant herein is not specifically identified as to each and every count.

VII. Plaintiffs' Experiences with Lap-Band®

102. Plaintiff Crocker suffered Lap-Band® erosion into and through her stomach wall resulting in gastric leakage, the development of sepsis, abdominal infection, tachycardia, intra-abdominal abscesses and peritonitis. The Lap-Band® was surgically removed from Plaintiff Crocker on February 9, 2015. Plaintiff Crocker also suffered, *inter alia*: cardiac arrest as a result of intra-abdominal abscess infection and peritonitis; distal esophagus and irregularly thickening of the cardia of the stomach; and developed chronic atrial fibrillation with significant deconditioning and loss of mobility.

103. Plaintiff Hackman suffered Lap-Band® erosion into her stomach. The Lap-Band® was surgically removed from Plaintiff Hackman on August 5, 2015. Plaintiff Hackman also suffered, *inter alia*: epigastric pain, distal esophagus, peptic ulcer disease, and severe abdominal bloating; multiple gastric fistula and gastroparesis; an eroded foreign body requiring subsequent surgery to remove the same; subsequent insertion and removal of feeding devices; and subsequent surgeries to repair esophageal injuries.

104. Plaintiff Roberts suffered Lap-Band® erosion into her stomach, leading to sepsis. The Lap-Band® was surgically removed from Plaintiff Roberts on December 5, 2014. Plaintiff Roberts also suffered, *inter alia*: severe abdominal pain, and anxiety and depression.

VIII. Defendant Scott

105. Defendant Scott is a duly licensed medical doctor, with his current office located in Lee Summit, Missouri.

106. At all relevant times herein, Defendant Scott was a duly licensed medical doctor with his office located in St. Louis County (at Des Peres Hospital) or Boone County (University of Missouri Hospital).

107. Defendant Scott focuses his medical practice on bariatric, complex gastrointestinal, and abdominal surgery, regularly or in the past regularly, performing Lap-Band® surgeries.

108. Upon information and belief, at certain relevant times herein, Defendant Scott was employed at or for Des Peres Hospital (located in St. Louis County, Missouri), St. Louis Bariatric Specialists, LLC, (located in St. Louis County, Missouri) or the University of Missouri-Columbia Hospital (located in Boone County, Missouri), and/or Defendant Scott provided medical treatment to Plaintiff Hackman at the foregoing locations.

109. Defendant Scott provided ongoing medical care and treatment to Plaintiff Hackman throughout 2016, specifically in regards to the complications and consequences of the implantation and removal of her Lap-Band®.

110. On September 16, 2016, Plaintiff Hackman underwent a partial gastrectomy under the direction and medical care of Defendant Scott.

111. Defendant Scott was caused to abort the partial gastrectomy on Plaintiff Hackman because of an iatrogenic esophageal perforation caused or contributed to be caused by the medical negligence of Defendant Scott.

112. As a result of suffering an esophageal perforation, Plaintiff Hackman was caused to require feeding tubes, suffered other injuries, and unwent additional surgeries.

IX. Defendant Minkin

113. Defendant Minkin is a duly licensed medical doctor, with his current office located in St. Louis County, Missouri.

114. At all relevant times herein, Defendant Minkin was a duly licensed medical doctor with his office located in St. Louis County (at Des Peres Hospital). At all relevant times, Defendant Minkin was a resident of St. Louis County, Missouri.

115. Defendant Minkin focuses his medical practice on bariatric, complex gastrointestinal, and abdominal problems, illness and surgery, regularly or in the past regularly, performing Lap-Band® surgeries.

116. Upon information and belief, at certain relevant times herein, Defendant Minkin was employed at or for Des Peres Hospital (located in St. Louis County, Missouri), St. Louis Bariatric Specialists, LLC (located in St. Louis County, Missouri), and/or Defendant Minkin provided medical treatment to Plaintiff Hackman at the foregoing locations.

117. Defendant Minkin provided ongoing medical care and treatment to Plaintiff Hackman from on or before 2010 through 2018, specifically in regards to the implantation and complications and consequences of the implantation and removal of her Lap-Band®.

118. On or about February 25, 2010, Plaintiff Hackman underwent the implant of the Lap-band ® device under the direction and medical care of Defendant Minkin.

119. On or about August 5, 2015, Defendant Minkin removed the Lap-Band® device at Des Peres Hospital, located in St. Louis County, Missouri. Since on or about February 25, 2010, and the present date in 2018, Defendant Minkin has provided continuous care to Plaintiff Hackman for problems associated with the implantation of the Lap-Band® device.

120. As a result of the implantation of the Lap-Band® device, Plaintiff Hackman has suffered erosion of the Lap-Band's® gastric band hardware, leading to epigastric pain, distal esophagus, peptic ulcer discharge, severe abdominal bloating, multiple gastric fistula and gastroparesis; and eroded foreign body, requiring surgery to remove the Lap-Band® device; subsequent insertion and removal of feeding devices; surgeries to repair abdominal injuries resulting from the implantation of the Lap-Band® device; and subsequent surgeries to repair esophageal injuries.

COUNT I
NEGLIGENT FAILURE TO WARN
(Against Lap-Band® Defendants)

121. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

122. At all relevant times, Lap-Band® Defendants were engaged in the business of designing, formulating, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising the Lap-Band® device for weight loss, including Plaintiffs.

123. The FDCA requires medical device manufacturers, such as Defendants, to maintain and submit information required by FDA regulation, 21 U.S.C. § 360i. This includes submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Lap-Band® Defendants were also required to keep abreast of all reports in the scientific literature concerning the Lap-Band®, including unpublished reports, including any clinical investigations or nonclinical laboratory studies involving the device or related devices known to or that reasonably should be known to the Lap-Band ® Defendants, and submit a summary and

bibliography concerning these reports pursuant to 21 C.F.R.§ 814.84. The FDA's PMA letter of June 2001 also required these submissions.

This federally mandated duty is paralleled by a similar Missouri state law duty to warn that a product, such as the Lap-Band®, has a particular defect or hazard, such as band erosion, or high rate of re-operation or band removal. Under Missouri law, a product manufacturer, like the Lap-Band® Defendants, also has a duty to investigate whether a product is safe for use, including reviewing and analyzing data concerning the safety of a device as part of their duty to warn of product defects or hazards.

124. Lap-Band® Defendants also had a duty under Missouri state law to exercise reasonable care to provide adequate and accurate warnings about the dangers and risks of the Lap-Band® that were known, or knowable, to Lap-Band® Defendants at the time of the distribution of the Lap-Band®. Under Missouri law, Lap-Band® Defendants had the duty to also convey these warnings to third-parties, like the FDA, when such information was then likely to reach physicians and patients.

125. According to the Conditions for Approval set forth in the PMA letter, Defendants have a continuing duty to monitor the Lap-Band®. Lap-Band® Defendants had a duty to submit reports to the FDA annually including data on adverse events, and histological explants data following any removal surgeries. Lap-Band® Defendants also have an ongoing duty to provide updated warnings and instructions regarding risks associated with the Lap-Band®.

126. The Lap-Band® Defendants breached their duty to warn by failing to communicate to the FDA Adverse Event Reports prior to the time of Plaintiffs' implants, thereby failing to warn Plaintiffs and their implanting physicians. By failing to warn the FDA through Adverse Event Reports of serious defects and complications described herein that Lap-Band®

Defendants knew or should have known were associated with the Lap-Band®, Lap-Band® Defendants breached their duty to Plaintiffs and their implanting physicians.

127. The FDA publishes the adverse events and MDRs shared by manufacturers in a public, searchable database called MAUDE. The MAUDE database is updated monthly with "all reports received prior to the update." Had Lap-Band® Defendants timely and adequately reported the adverse events as required by federal and state law, additional information would have been available to Plaintiffs and/or Plaintiffs' physicians regarding the dangers of the Lap-Band® that were known or knowable to Defendants at the time of Plaintiffs' implant procedures.

128. Lap-Band® Defendants also had a parallel duty under Missouri state law to exercise reasonable care in warning the public and third parties about the risks and dangers of the Lap-Band® known or knowable to them at the time of Plaintiffs' implant procedures.

129. Specifically, Lap-Band® Defendants breached these duties and violated federal and parallel Missouri law by:

A. Failing to report and actively concealing complaints of Lap-Band® erosion, including perforations of the stomach, esophagus and bowel which were caused by the Lap-Band®;

B. Failing to report instances of Lap-Band® reoperations;

C. Failing to report instances of Lap-Band® removal;

D. Failing to report instances of serious adverse events requiring the Lap-Band® removal or reoperations;

E. Failing to comply with the specific reporting requirements outlined in the PMA.

F. Failing to submit a PMA supplement when increases in Lap-Band® serious adverse events, including erosion were known or should have been known; and

G. Failing to disclose numerous complaints to the FDA as medical device reports.

130. If Lap-Band® Defendants had properly and timely reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physicians, of those adverse events by, among other things, providing more complete information through the FDA's MAUDE database, and/or through a PMA supplement.

131. If Plaintiffs had been aware of these adverse events, they would not have agreed to the Lap-Band® implants and, upon information and belief, their physicians would not have recommended the implant for them.

132. Lap-Band® Defendants negligently failed to comply with the above requirements and failed to take the necessary actions, such as filing PMA supplements, updating the label pursuant to 21 C.F.R. § 820.39(d), or submitting MDRs, to timely advise the potential The Lap-Band® users of the above- described defects and risks.

133. As a proximate and legal result of Lap-Band® Defendants' failure to comply with its PMA, federal regulations and parallel Missouri law requirement, they breached their duty of care to Plaintiffs and caused Plaintiffs past and future suffering, including severe physical injuries, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;

e. punitive or exemplary damages in the amount of $3 million; and

f. such other relief and further relief as this Court may deem just and proper.

COUNT II
NEGLIGENCE
(Against Lap-Band® Defendants)

134. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

135. Lap-Band® Defendants were and are under a continuing duty to comply with federal requirements, including the PMA, its Supplements, the Conditions of Approval, and with the FDCA in the manufacture, development, design, marketing, labeling, distributing, and sale of the Lap-Band® and its implementing.

136. Lap-Band® Defendants concealed material information related to the safety of the Lap-Band® device and deceptively and falsely underreported the dangerous propensities and increased risks of the Lap-Band®.

137. Lap-Band® Defendants' Conditions of Approval expressly provided that "continued approval of this PMA is contingent upon the submission of post-approval reports required under 21 C.F.R. § 814.84...."

138. The information required to be submitted included, in part, information that is known or reasonably should be known to the applicant and shall include published and unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices.

139. It was the duty of Lap-Band® Defendants to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Lap-Band® Defendants violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the following ways:

A. 21 U.S.C. § 352(a) because Lap-Band® Defendants aggressively marketed the Lap-Band® directly to consumers through false advertising. Falsely stating the Lap-Band® is safer and just as effective as gastric bypass, the falsity evidenced by, among other things, numerous medical studies that indicate that gastric bypass is a more effective wright loss procedure with a lower long-term complication rate, a lower re-operation rate and a lower long-term failure rate. Moreover, while 21 C.F.R. 99.101 allows manufacturers to disseminate written information concerning the safety, effectiveness, or benefit from the use of their product that is not described in the FDA approved label, such information must not be false or misleading. 21C.F.R. 99.101(a)(4). Such information can be false or misleading if, for no other reason, "the information includes only favorable publications when unfavorable publications exist...." 21 C.F.R. 99.101(a)(4). Submitting false or misleading information to consumers to entice them to purchase a product is also prohibited by Missouri law.

B. 21 U.S.C. § 352(q) because Lap-Band® Defendants created and distributed false and misleading advertising for the Lap-Band® because the Lap-Band® is not a safer and more effective method of weight loss than gastric bypass, evidenced by numerous the Lap-Band® studies indicating that patients who undergo the Lap-Band® procedure are more likely to experience injuries and long-term complications which require surgical intervention or re-operation, including band erosion.

C. 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Lap-Band® Defendants failed to report and/or timely

report adverse events, including but not limited to, complaints of device migration, perforation and erosion of the Lap-Band® into the stomach wall and esophagus and surgical removal of the Lap-Band® device, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiff to undergo surgical intervention to prevent further injury.

D. 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Lap-Band® Defendants failed to report new clinical investigations and/or scientific studies concerning the Lap-Band® device about which Lap-Band® Defendants knew or reasonably should have known about indicating a higher band erosion rate than that reported by the Lap-Band® Defendants to the FDA to obtain PMA.

E. 21 U.S.C. §§ 360(q); 360(r) because Lap-Band® Defendants created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of the Lap-Band® in order to convince physicians and patients to use the Lap-Band® over other methods of weight loss, thereby gaining market share.

F. 21 C.F.R. § 820.198 because Lap-Band® Defendants failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, erosion of the stomach wall and/or esophagus, infection and removal of the device.

G. 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Lap-Band® Defendants (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of erosion of the stomach wall and/or esophagus, infection, device failure, and surgery to remove or attempt to repair/fix the device, which strongly

indicated the Lap-Band® device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in a patient's body, and (2) Lap-Band® Defendants continued to sell the Lap-Band® into the stream of interstate commerce when they knew, or should have known, that the Lap-Band® was malfunctioning or otherwise not responding to its Design Objective Intent.

H. 21 C.F.R. § 814.80 because Lap-Band® Defendants manufactured, packaged, stored, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

I. 21 C.F.R. § 820.30 because Lap-Band® Defendants failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to stomach and esophagus erosion, infection, device migration, and/or device fracture/breakage.

J. 21 C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Lap-Band® Defendants: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of stomach and esophagus erosion, infection, and/or device migration; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and

(4) failed to take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues.

K. 21 C.F.R. § 820.70 because Lap-Band® Defendants failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of nonconforming products, including but not limited to stomach wall erosion, device migration, re-operation and device failure.

L. 21 C.F.R. § 814.39 because Lap-Band® Defendants failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the numerous reported and unreported adverse events consisting of serious injuries, by the numerous The Lap-Band® studies consisting of numerous individuals reporting that patients who undergo the Lap-Band® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation.

140. As a direct and proximate result of Lap-Band® Defendants' violations of one or more of the above federal statutory and regulatory standards of care, and parallel Missouri State law duties, the Lap-Band® device was implanted in Plaintiffs, were not removed from Plaintiffs prior to injury, and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3. Plaintiff were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

141. Lap-Band® Defendants failed to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of the Lap-Band®.

142. This cause of action is based entirely on the contention that Lap-Band® Defendants violated federal safety statutes and regulations and parallel Missouri State law duties. Plaintiffs do not bring the underlying action as an implied statutory cause of action, but rather Plaintiffs are pursuing parallel state common law claims based on Lap-Band® Defendants' violations of the applicable federal regulations. Plaintiff is not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Lap-Band® Defendants' conduct violates these provisions. Rather Plaintiffs are alleging that Defendants' conduct that violates these provisions also violates parallel state laws.

143. Lap-Band® Defendants' violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence in tort under state common law.

144. Thus, for violation of federal law including but not limited to the FDCA, the MDA and relevant regulations which results in an unreasonably dangerous product proximately causing injuries there already exists a money damages remedy under state common law.

145. Lap-Band® Defendants owed Plaintiffs and Plaintiffs' physicians the duty to exercise reasonable or ordinary care under the circumstances, in light of the generally-recognized and prevailing best scientific knowledge.

146. Lap-Band® Defendants had a confidential and special relationship with Plaintiffs due to their vastly superior knowledge of the health and safety risks relating to The Lap-Band®.

147. As a result, Lap-Band® Defendants had an affirmative duty to fully and adequately warn Plaintiffs and Plaintiffs' physicians of the true health and safety risks related to the use of The Lap-Band®. Independent of any special relationship of confidence or trust, Lap-Band®

Defendants had a duty not to conceal the dangers of The Lap-Band® from Plaintiffs and Plaintiffs' physicians.

148. Misrepresentations made by Lap-Band® Defendants about the health and safety of The Lap-Band® not part of any FDA approval label or advertising independently imposed a duty upon Lap-Band® Defendants to fully and accurately disclose to Plaintiffs and Plaintiffs' physicians the true health and safety risks related to The Lap-Band®.

149. Through the conduct described in the foregoing and subsequent paragraphs of this Petition, Lap-Band® Defendants breached their duties to Plaintiffs and to Plaintiffs' physicians.

150. The following sub-paragraphs summarize, *inter alia*, Lap-Band® Defendants' breaches of duties to Plaintiffs and Plaintiffs' physicians and describe categories of acts or omissions constituting breaches of duty by Lap-Band® Defendants. Each and/or any of these acts or omissions establishes an independent basis for their liability in negligence:

A. Unreasonable and improper promotion and marketing of the Lap-Band® directly to consumers, including Plaintiffs;

B. Unreasonable and improper promotion and marketing of the Lap-Band® to physicians;

C. Failure to warn the FDA, Plaintiffs and Plaintiffs' physicians of the dangers associated with the long-term implantation of the Lap-Band® when such information was available to the Lap-Band® Defendants; or

D. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale, and marketing of The Lap-Band®. Under federal law, Lap-Band® Defendants had a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any complaints about

the product's performance and any adverse health consequences that are or may be attributable to the product.

151. Lap-Band® Defendants violated their duties under federal law to report adverse event information to the FDA. Lap-Band® Defendants failed to comply with their independent but parallel duty under Missouri law.

152. Settled state common law protects the safety and health of its citizens by imposing a general duty of reasonable care on product manufacturers. Moreover, state common laws include causes of action for failure to warn. A product is unreasonably dangerous in the absence of adequate warnings under applicable state common laws.

153. Lap-Band® Defendants failed to use reasonable care and failed to adequately warn as to the increased risks and dangers of The Lap-Band®. As a result of these wrongful actions, the Plaintiffs were caused to suffer severe injuries and to incur significant damages.

154. Lap-Band® Defendants knew, or should have known, that due to their failure to use reasonable care, Plaintiffs and Plaintiffs' physicians would use and did use The Lap-Band® to the detriment of Plaintiffs' health, safety and well-being.

155. As the direct, producing, proximate and legal cause and result of Lap-Band® Defendants' negligence, Plaintiffs suffered severe injuries.

156. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

157. Lap-Band® Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. compensatory damages according to proof;

c. costs of litigation;

d. post-judgment interest;

e. punitive or exemplary damages in the amount of $3 Million Dollars; and

f. such other relief and further relief as this Court may deem just and proper.

COUNT III
NEGLIGENCE PER SE
(Against Lap-Band® Defendants)

158. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

159. It was the duty of Lap-Band® Defendants to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Lap-Band® Defendants violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the following ways:

A. 21 U.S.C. § 352(q) because Lap-Band® Defendants created and distributed false and misleading advertising for the Lap-Band® which is a "Restricted Device" because the Lap-Band® is not a safer and more effective method of weight loss than alternative methods, such as gastric bypass, evidenced by the numerous reported adverse events consisting of serious injuries, by the numerous The Lap-Band® studies reporting that patients who undergo the Lap-Band® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by numerous medical studies indicating the Lap-Band® is not as effective in helping patients lose weight or cure co-morbidities as gastric bypass.

B. 21 C.F.R. § 803.50; 21 C.F.R: § 814.80, and 21 U.S.C. § 360i(a), because Lap-Band® Defendants failed to inform and report and/or timely report adverse events to the FDA, including but not limited to, complaints of device migration, device erosion, erosion of the stomach wall, higher reoperation rates, higher rates of device removal and device failure, all of which are serious adverse events, which lead or may lead to a serious injury and which caused Plaintiffs

to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

C. 21 C.F.R. § 814.84(b)(2) because Lap-Band® Defendants failed to report new clinical investigations and/or scientific studies concerning the Lap-Band® device about which Lap-Band® Defendants knew or reasonably should have known which reported increases incidents of adverse events, device erosion, high re-operation rates, high device removal rates and high device failure rates.

D. 21 U.S.C. §§ 360(q); because Lap-Band® Defendants created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of The Lap-Band® in order to convince physicians and patients to use The Lap-Band® over other methods of weight loss, thereby gaining market share.

E. 21 C.F.R. § 820.198 because Lap-Band® Defendants failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device erosion and migration, stomach wall perforation, high reoperation and device failure rates, and other problems associated with the Lap-Band® device.

F. 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Lap-Band® Defendants (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of erosion of the stomach wall and esophagus, which strongly indicated the Lap-Band® device was malfunctioning or otherwise not responding to its Design Objective Intent, and (2) Lap-Band® Defendants continued to sell the Lap-Band® into the stream of interstate commerce when

they knew, or should have known, that the Lap-Band® was malfunctioning or otherwise not responding to its Design Objective Intent.

G. 21 C.F.R. § 814.80 because Lap-Band® Defendants manufactured, packaged, stored, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

H. 21 C.F.R. § 814.39 and Lap-Band® Defendants June 2001 PMA letter because Lap-Band® Defendants failed to submit and/or timely submit a PMA supplement to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the numerous reported and unreported adverse events consisting of serious injuries, by the numerous the Lap-Band® studies consisting of numerous reports that patients who undergo the Lap-Band® procedure are more likely to experience long-term complications which require or will require surgical intervention or re-operation, and by unreported complaints contained in Lap-Band® Defendants' complaint files.

I. 21 C.F.R. § 99.101 because Lap-Band® Defendants made false and misleading statements in written information they disseminated concerning the Lap-Band®'s safety and effectiveness, including, but not limited to, including only favorable publications when unfavorable publications existed and making statements about the safety and effectiveness of the Lap-Band® that are demonstrably untrue. As otherwise noted herein, Lap-Band® Defendants; made statements on T.V., on the internet and in brochures that the Lap-Band® was "safer but just as effective as gastric bypass", "up to 10 times safer than

gastric bypass" that the Lap-Band® was the "[o]nly surgical option designed to maintain long-term weight loss" and that the Lap-Band® had "fewer risks and side effects than gastric bypass."

160. As a direct and proximate result of Lap-Band® Defendants' violations of one or more of the above federal statutory and regulatory standards of care, the Lap-Band® device was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injuries, as defined in 21 C.F.R. § 803.3.

161. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

162. Lap-Band® Defendants failed to act as a reasonably prudent Class III medical device manufacturer, distributor, and/or promoter.

163. Plaintiffs are not seeking to enforce these federal provisions in this action. Likewise, Plaintiffs are not suing merely because Lap-Band® Defendants' conduct violates these provisions. Rather Plaintiffs are alleging that Lap-Band® Defendants' conduct that violates these provisions also violates parallel state laws.

164. Lap-Band® Defendants' violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence in tort under state common law.

165. Thus, for violation of federal law including but not limited to the FDCA, the MDA and relevant regulations which results in an unreasonably dangerous product proximately causing injuries there already exists a money damages remedy under state common law. Lap-Band® Defendants' violations of these federal statutes and regulations caused Plaintiffs' injuries.

166. Plaintiffs' injuries resulted from an occurrence the laws and regulations were designed to prevent.

167. Plaintiffs are a persons whom these statutes and regulations were meant to protect.

168. Lap-Band® Defendants' violations of these statutes or regulations constitutes negligence per se.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. compensatory damages according to proof;

c. costs of litigation;

d. post-judgment interest;

e. punitive or exemplary damages in the amount of $3 Million; and

f. such other relief and further relief as this Court may deem just and proper.

COUNT IV
NEGLIGENT MISREPRESENTATION
(Against Lap-Band® Defendants)

169. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

170. Lap-Band® Defendants made untrue representations and omitted material information to Plaintiffs and Plaintiffs' physicians at all times material to this Petition by publically stated though aggressive T.V., Internet and written advertisement that the Lap-Band® is "safer but just as effective as gastric bypass", "up to 10 times safer than gastric bypass" that the Lap-Band® procedure is the "[o]nly surgical option designed to maintain long-term weight loss," and that the Lap-Band® system has "fewer risks and side effects" than gastric bypass. None

of these statements were approved by the FDA nor were they part of the FDA approval labeling. Most importantly, all of these statements are demonstrably false.

171. Lap-Band® Defendants have also stated through their T.V., Internet and print advertising that the total number of complications for the Lap-Band® procedure are 9% while the total number of complications for gastric bypass are 23%, that major complications for the Lap-Band® procedure are 0.2% while major complications for gastric bypass are 2.1%. Additionally, Defendant Allergan in its 2007 www.Lapband.com website describes the complication of Lap-Band® erosion as requiring "minor revisional surgery". Defendant Allergan makes this false claim to compare the Lap-Band® System to gastric bypass's complications of the "separation of stapled areas" or "leaks from staple lines" which Defendant Allergan describes as requiring "major revisional surgery."

Defendant Allergan's promise that band erosion requires only "minor revisional surgery" is directly contradicted by the way band erosion is described in the warning label approved by the FDA which states that band erosion is a "severe adverse event", that "[r]e-operation to remove the device is required", and that "[r]e-operation for band erosion may result in gastrectomy" – which is surgical removal of part or all of the stomach. Defendant Allergan's statement that the complication of band erosion requires only "minor revisional surgery" was never approved by the FDA, is not true and is also proven to be a misrepresentation not only as indicated in this count of the Petition but by the numerous medical studies cited within this Petition.

Lap-Band® Defendant's statement that the Lap-Band® has only a 9% total complication rate was never approved by the FDA and is, once again, directly contradicted by not only numerous medical studies, but by information that Lap-Band® Defendants' conveyed

directly to the FDA seeking PMA for the Lap-Band®. Lap-Band® Defendants stated that in the results of their clinical trials submitted to the FDA that 89% of the subjects reported at least one adverse event, including 17% of the patients having to have their Lap-Band® removed. Moreover, thirty-four percent (34%) of patients in the clinical study submitted to the FDA reported at least one "severe adverse event". A "severe adverse event" is defined as causing "severe discomfort as such that patient cannot perform daily activities. Severity may result in cessation of treatment or required removals of the devices, or treatment of symptoms may be given and/or patient hospitalized".

In support of Lap-Band® Defendants contention that the Lap-Band® has only a 9% total complication rate it cites only one article - - O'Brien P, Dixon J. Lap-Band®: *Outcome and results, J. of Laparoendosc & Adv. Surg. Techniques*, 13(4), 2003, 265-270. First, Lap-Band® Defendants citing only medical articles that support its contention when there are numerous medical articles concluding the total complication rate is much higher than 9% is prohibited by 21 C.F.R. § 99.101 which allows a manufacture to disseminate written information concerning the safety or effectiveness that is not described in the labeling only if, among other things, it is not "false or misleading" 21 C.F.R. § 99.101(a)(4). "Moreover, information can be considered fake or misleading", "if, among other things, the information includes only favorable publications when unfavorable publications exist... "21 C.F.R. § 99.101(a)(4). The Lap-Band® Defendants marketing statement that there is an only 9% total complication rate not only contradicts the information they gave to the FDA, and is contradicted by numerous medical studies, some of which are described herein, the medical article they cite to support the contention of a 9% complication rate's lead author, Dr. Paul O'Brien, has received funding from Defendant Allergan, and was the National Medical

Director of the Texas based True Results clinics which launched an extensive television marketing campaigns for the Lap-Band® and had a vested financial interested in promoting the effectiveness of the device.

172. Lap-Band® Defendants knew or should have known their representations were false when they were made.

173. Plaintiffs would not have chosen the Lap-Band® procedure as a method of weight loss had they known of the true safety risks related to The Lap-Band®.

174. Lap-Band® Defendants were negligent in making the false misrepresentations and omitting material information because Lap-Band® Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their The Lap-Band® device.

175. Lap-Band® Defendants intended to induce Plaintiffs to rely on their misrepresentations and omissions to use The Lap-Band® over the alternative methods of weight loss.

176. Plaintiffs were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to The Lap-Band® in deciding to undergo the Lap-Band® procedure for weight loss.

177. Plaintiffs were justified in their reliance on Lap-Band® Defendants' representations and marketing. Plaintiffs actually did undergo the Lap-Band® implant procedure, which ultimately caused Plaintiffs serious physical injury.

178. In agreeing to undergo a procedure whereby the Lap-Band® was implanted, Plaintiffs justifiably relied on such misrepresentations by Lap-Band® Defendants. As the direct, producing, proximate and legal cause and result of Lap-Band® Defendants' misrepresentations, Plaintiffs have suffered severe physical pain, medical and hospital expenses, pain and suffering, and pecuniary loss.

179. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

180. Lap-Band® Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. compensatory damages according to proof;

c. costs of litigation;

d. post-judgment interest;

e. punitive or exemplary damages in the amount of $3 Million; and

f. such other relief and further relief as this Court may deem just and proper.

COUNT V
STRICT LIABILITY – FAILURE TO WARN
(Against Lap-Band® Defendants)

181. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

182. Lap-Band® Defendants designed, formulated, tested, packaged, labeled, produced, created, assembled, advertised, manufactured, sold, distributed, marketed, and promoted The Lap-Band®, including the Lap-Band® devices that were implanted into Plaintiff.

183. Lap-Band® Defendants at all times herein were medical device manufacturers and subject to the Medical Device Reporting regulations under 21 C.F.R. § 803.

184. Lap-Band® Defendants had a duty to warn the FDA about the dangers of the Lap-Band® device, which they knew, or in the exercise of ordinary care, should have known, at the time the Lap-Band® device left their control, pursuant to 21 C.F.R. § 803.50.

185. Lap-Band® Defendants did know of these increased risks and serious dangers and breached their duty by failing to warn the FDA of same.

186. Lap-Band® Defendants also had a continuing obligation to exercise reasonable care in warning third-parties, including the FDA, when it can reasonably be assumed the third-parties will warn Plaintiffs and/or their physicians of potential dangers under parallel state law duties, which includes warning the FDA of dangers and adverse events associated with the Lap-Band® device that were known, or should have been known by Defendants at the time of distribution.

187. At the time the Lap-Band® devices left control of Lap-Band® Defendants when they was implanted into Plaintiffs, it was unreasonably dangerous due to non-compliance by Lap-Band® Defendants with the FDCA, and the regulations promulgated pursuant to it, including but not limited to, in one or more of the following ways:

A. 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because Lap-Band® Defendants failed to report and/or timely report adverse events, including but not limited to, complaints of device erosion, migration, perforation, erosion of the stomach wall, re-operation and removal rate and device failure rate, all of which are serious injuries or may lead to serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

B. 21 C.F.R. § 814.84(b)(2) because Lap-Band® Defendants failed to report new clinical investigations and/or scientific studies concerning the Lap-Band® device about which Lap-Band® Defendants knew or reasonably should have known about.

C. 21 C.F.R. § 820.198 because Lap-Band® Defendants failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints of, but not limited to, device migration, perforation, long-term complications, re-operations, device removal and devise failure, and other quality problems associated with the Lap-Band® device.

D. 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Lap-Band® Defendants (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration, and Lap-Band®, stomach wall erosion, which strongly indicated the Lap-Band® device was malfunctioning or otherwise not responding to its Design Objective Intent,

and (2) Lap-Band® Defendants continued to sell the Lap-Band® into the stream of interstate commerce when they knew, or should have known, that the Lap-Band® was malfunctioning or otherwise not responding to its Design Objective Intent.

E. 21 U.S.C. §§ 360(q); 360(r) because Lap-Band® Defendants created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of The Lap-Band® in order to convince physicians and patients to use The Lap-Band® over other methods of weight loss, thereby gaining market share.

F. 21 C.F.R. § 814.80 because the Lap-Band® device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

G. 21 C.F.R. § 820.30 because Lap-Band® Defendants failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage.

H. 21 C.F.R. § 814.39 and the PMA letter of June 2001, because Lap-Band® Defendants failed to submit and/or timely submit a PMA supplement to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal

association; such evidence is the numerous reported and unreported adverse events consisting of serious injuries, by the numerous the Lap-Band® studies consisting of patients who undergo the Lap-Band® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the unreported complaints contained in Lap-Band® Defendants' complaint files.

188. As a direct and proximate result of Lap-Band® Defendants' violations of one or more of the above federal statutory and regulatory standards of care, the Lap-Band® device was implanted in Plaintiffs, Plaintiffs did not have the device removed prior to injury, and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

189. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

190. Lap-Band® Defendants failed to act as a reasonably prudent Class III medical device manufacturer, distributor, and/or promoter.

191. Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because Lap-Band® Defendants' conduct violates these provisions. Rather Plaintiffs are alleging that Lap-Band® Defendants' conduct that violates these provisions also violates parallel state laws.

192. Lap-Band® Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of strict liability in tort under state common law.

193. Thus, for violations of federal law, including the FDCA, the MDA, and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, there already exists a money damages remedy under state common law.

194. The warnings accompanying the Lap-Band® device did not adequately warn Plaintiffs and Plaintiffs' physicians, in light of Lap-Band® Defendants' scientific and medical knowledge at the time, of the increased risks and serious dangers associated with the Lap-Band® device, including but not limited to Lap-Band® erosion, re-operation rates, removal rates and Lap-Band® failure rates.

195. In direct violation of 21 C.F.R. § 803.50 as well as State regulations and/or common law, Lap-Band® Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the Lap-Band® when annually reported to the FDA, including Lap-Band® erosion, erosion of the stomach wall and/or esophagus and organ perforation, re-operation, removal and device failure.

196. The FDA, Plaintiffs and Plaintiff's physicians were unaware of Lap-Band® Defendants' omissions and this led to Plaintiffs and Plaintiffs' physicians' reliance on Lap-Band® Defendants' inadequate warnings in deciding to use The Lap-Band®.

197. Plaintiffs and Plaintiffs' physicians' did not and could not know of the specific increased risks and serious dangers of The Lap-Band®, and/or were misled by Lap-Band® Defendants, who knew of or should have known of the true risks and dangers of the Lap-Band® based on the number of complaints reported directly to them as well as the reports in the medical and scientific literature that they knew or should have known about.

198. Lap-Band® Defendants consciously chose not to inform the FDA, thereby preventing Plaintiffs and Plaintiffs' physicians from having the information necessary to make an informed decision when deciding to recommend and undergo the Lap-Band® procedure.

199. The FDA publishes adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with all reports received prior to the update.[2] The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

200. If Lap-Band® Defendants had met their duties under federal law and parallel state law, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians, of the increased risks and serious dangers associated with the Lap-Band® in time to have lessened or prevent Plaintiffs' injuries.

201. Additionally, if Lap-Band® Defendants had met their duty under 21 C.F.R. § 803.50, such information would have been made available to Plaintiffs and Plaintiffs' treating physician, which would have allowed Plaintiffs' treating physician to properly and/or timely diagnose the cause of Plaintiffs' health problems.

202. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, and of the Lap-Band® Defendants' failure to provide adequate warnings about them, as required under 21 C.F.R. § 803.50, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

203. Plaintiffs have sustained extreme pain, suffering, and anguish and has otherwise suffered serious injuries and damages.

[2] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

204. Lap-Band® Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;
e. punitive or exemplary damages in the amount of $3 Million; and
f. such other relief and further relief as this Court may deem just and proper.

COUNT VI
COMMON LAW FRAUD
(Against Lap-Band® Defendants)

205. Plaintiff Crocker incorporates by reference all paragraphs of this Petition as if fully set forth herein.

206. Plaintiff Crocker brings a claim against Lap-Band® Defendants for knowingly concealing information relative to the Lap-Band® device, and knowingly making false statements regarding the Lap-band® device.

207. Lap-Band® Defendants committed fraud by concealing and/or making fraudulent representations during their promotional practices concerning the Lap-Band® device that were not approved by the FDA and/or the FDA premarket approval process.

208. In connection with the Lap-Band® product, Lap-Band® Defendants fraudulently and intentionally misrepresented material and important health and safety product risk

information to Plaintiff Crocker and Plaintiff's physicians, that were not approved by the FDA and/or the FDA premarket approval process. The specifics regarding the content of the misrepresentations, when and where Lap-Band® Defendants made them, and to whom they were made, as well as what aspects of the statements were misleading and why, are alleged below.

209. Plaintiff Crocker had her Lap-Band® device implanted in and around December 2007. In the month leading up to the implant surgery Plaintiff Crocker saw T.V. advertising regarding the Lap-Band® device, visited the Lap-Band® Website, and attended a dinner/seminar concerning the Lap-Band® device.

210. When Plaintiff Crocker visited the Lap-Band® website, www.Lapband.com, she saw the following statements, among others, on the Lap-Band® Defendant Website: The Lap-Band® is the "[o]nly surgical option designed to help maintain long-term weight loss" the Lap-Band® device is the "[s]tandard of care for hundreds of surgeons around the world"; that "surgeons report that at 5 years many Lap-Band® and gastric bypass patients achieve comparable weight loss (55% for Lap-Band® and 59% for gastric bypass)", citing O'Brien, P., Dixon, J., *Lap-Band®! Outcome and Results*, J. of Laparoend § Adv. Surg. Techniques, 13(4); 2003:265-270. Plaintiff Crocker also saw on the website the statement that the total complication rates for the Lap-Band® was 9%, while the total complication rate for gastric bypass was 23%, that with the Lap-Band® there was a major complication rate of 0.2%, which with the gastric bypass there was a major complication rate of 2.1%, that band erosion with the Lap-Band® required only "minor revisonal surgery" while separation of stapled areas or leaks from stapled line with gastric bypass required "major revisonal surgery". The website also said the Lap-Band® had fewer risk and side effects than gastric bypass.

None of the above statements were approved or reviewed by the FDA and none of these statements are true.

211. Plaintiff Crocker would not have decided to use the Lap-Band® or would have had the Lap-Band® removed prior to injury had she known of the real increased risks and dangers related to the Lap-Band®:

A. Any of the false statements described herein is sufficient to independently establish defendant's liability for fraudulent misrepresentations concerning the health and safety hazards, symptoms, constellation of symptoms and/or health problems associated with the Lap-Band®;

B. Lap-Band® Defendants fraudulently misrepresented information about the known increased risks and dangers as well as the limited benefits of the use of the Lap-Band® and the relative benefits and availability of alternate options.

212. As a medical device manufacturer, Lap-Band® Defendants had an affirmative continuing duty to warn the public, including Plaintiffs and Plaintiffs' physicians regarding the increased risks and dangers they knew, learned, or should have known about associated with The Lap-Band®. Moreover, Lap-Band® Defendants have a duty under federal and parallel state law not to misrepresent the safety or effectiveness of the Lap-Band®.

213. Had the Lap-Band® Defendants not misrepresented the safety and effectiveness of the Lap-Band® device, Plaintiff Crocker would not have undergone the Lap-Band® implant procedure.

214. When Lap-Band® Defendants engaged in this deceptive campaign and made the above representations and/or omissions, they knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or

omissions were true. These representations and/or omissions were made by Lap-Band® Defendants with the intent of defrauding and deceiving the public, including PlaintiffCrocker, Plaintiff's physicians, and the medical community.

215. At the time the aforesaid representations and/or omissions were made by Lap-Band® Defendants, Plaintiff Crocker and her medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Lap-Band® Defendants' assertions, promulgated through aggressive sales tactics as set forth herein, that the safety and effectiveness of the Lap-Band®.

216. In reliance upon Lap-Band® Defendants' representations, each Plaintiff and Plaintiffs' physician used the Lap-Band®.

217. Had Plaintiff Crocker been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with use of the Lap-Band®, she would not have used it.

218. Lap-Band® Defendants' motive for making false statements Lap-Band® to Plaintiff Crocker was for financial gain, increased sales and market share.

219. Lap-Band® Defendants' conduct, as alleged above, was malicious, fraudulent, and oppressive toward Plaintiff Crocker in particular and the public generally, and Lap-Band® Defendants conducted themselves in a willful, wanton, and reckless manner by actively violating federal regulations.

220. Lap-Band® Defendants are guilty of malice, oppression, and fraud, and PlaintiffCrocker are therefore entitled to recovery of exemplary or punitive damages in sum according to proof at trial.

WHEREFORE, Plaintiff Crocker prays for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;
e. punitive or exemplary damages in the Amount of $3 Million; and
f. such other relief and further relief as this Court may deem just and proper.

COUNT VII
FRAUDULENT CONCEALMENT
(Against Lap-Band® Defendants)

221. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

222. In connection with their the Lap-Band® device, Lap-Band® Defendants fraudulently and intentionally concealed and suppressed the material and important health and safety product risk information described herein regarding the high long-term complication rate, the higher than 1% band erosion rate, the high re-operation rate and the high Lap-Band® failure rate from the FDA, Plaintiffs, and Plaintiffs' physicians, all as alleged in this Petition. Plaintiffs and Plaintiffs' physician would not have used the Lap-Band® for weight loss or would have had the Lap-Band® removed prior to injury had they known of these increased safety risks and dangers related to the Lap-Band®.

223. Lap-Band® Defendants fraudulently concealed and misrepresented the increased health and safety risks, dangers, hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the Lap-Band® device to physicians, including Plaintiffs' physicians; and

224. Lap-Band® Defendants fraudulently concealed and misrepresented material safety information about the known increased risks and dangers of the use of the Lap-Band® and the relative benefits and availability of alternate procedures.

225. Lap-Band® Defendants knew, or should have known, that they were concealing, suppressing, and misrepresenting true information about the known increased risks and benefits of the use of the Lap-Band® and the relative benefits and availability of alternate procedures.

226. Lap-Band® Defendants knew that Plaintiffs and Plaintiffs' physicians would regard the matters that they concealed, suppressed, and misrepresented to be important in determining the course of treatment for the Plaintiffs, including Plaintiffs and Plaintiffs' physicians' decision whether or not to use the Lap-Band® as a weight loss procedure.

227. Lap-Band® Defendants intended to cause Plaintiffs and Plaintiffs' physicians to rely on their concealment of material safety information, suppression, and misrepresentations about the increased risks and dangers related to the Lap-Band® as a method of weight loss.

228. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on Lap-Band® Defendants' concealment of information and misrepresentations about the increased safety risks and dangers related to the Lap-Band® in deciding to recommend and choose the Lap-Band® procedure for weight loss.

229. As a direct and proximate result of Lap-Band® Defendants' fraudulent concealment, suppression, and misrepresentations of the material increased health and safety risks and dangers relating to the Lap-Band® discussed herein and Lap-Band® Defendants' false promotion and marketing practices discussed herein, Plaintiffs suffered injuries and economic loss, and Plaintiffs will continue to suffer injuries, damages and economic loss.

230. As the direct, proximate, and legal cause and result of Lap-Band® Defendants' false and deceptive marketing and promotion practices related to the Lap-Band®, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, physical pain and suffering, and loss of the enjoyment of life.

231. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

232. Lap-Band® Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;
e. punitive or exemplary damages in the amount of $3 Million; and
f. such other relief and further relief as this Court may deem just and proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY
(Against Lap-Band® Defendants)

233. Plaintiffs Crocker and Hackman incorporate by reference all paragraphs of this Petition as if fully set forth herein.

234. The Lap-Band® Defendants between 2007 and 2010 publically stated though aggressive T.V., Internet and written advertisement that the Lap-Band® is "safer but just as effective as gastric bypass", "up to 10 times safer than gastric bypass" that the Lap-Band® procedure is the "[o]nly surgical option designed to maintain long-term weight loss," and that the Lap-Band® system has "fewer risks and side effects" than gastric bypass. None of these statements were approved by the FDA nor were they part of the FDA approval labeling. Most importantly, all of these statements are demonstrably false.

235. Lap-Band® Defendants have also stated through their T.V., Internet and print advertising between 2007 and 2010, that the total number of complications for the Lap-Band® procedure are 9% while the total number of complications for gastric bypass are 23%, that major complication for the Lap-Band® procedure are 0.2% while major complication for gastric bypass are 2.1%. Additionally, Lap-Band® Defendants described the complication of Lap-Band® erosion as requiring "minor revisional surgery". Lap-Band® Defendants made this false claim to compare the Lap-Band® System to gastric bypass's complications of the "separation of stapled areas" or "leaks from staple lines" which Lap-Band® Defendants described as requiring "major revisional surgery". None of these statements were approved by or reviewed by the FDA.

Lap-Band® Defendants' promise that band erosion requires only "minor revisional surgery" is directly contradicted by the way band erosion is described in the warning label approved by the FDA which states that band erosion is a "sever adverse event", that "[r]e-operation to remove the device is required", and that "[r]e-operation for band erosion may result in gastrectomy" – which is surgical removal of part or all of the stomach.

236. Lap-Band® Defendant's statement that the Lap-Band® has only a 9% total complication rate was never approved by the FDA and, is once again, directly contradicted by not only numerous medical studies, but by information that they conveyed directly to the FDA in seeking approval to sell the Lap-Band®. Lap-Band® Defendant stated that in the results of their clinical trials that 89% of the subjects reports at least one adverse event, including 17% of the patients having to have their Lap-Band® removed. Moreover, thirty-four percent (34%) of patients in the clinical study submitted to the FDA reported at least one "severe adverse event". A "severe adverse event" was defined by Lap-Band® Defendants as causing

"severe discomfort as such that patient cannot perform daily activities. Severity may result in cessation of treatment or required removals of the devices, or treatment of symptoms may be given and/or patient hospitalized".

237. In support of Lap-Band® Defendants contention that the Lap-Band® has only a 9% total complication rate they cite - - O'Brien P, Dixon J. Lap-Band®: *Outcome and results, J. of Laparoendosc & Adv. Surg. Techniques*, 13(4), 2003, 265-270. First, Lap-Band® Defendants citing only one medical article to support this contention when there are numerous medical articles concluding the total complication rate is much higher than 9% is prohibited by 21 C.F.R. § 99.101 which allows a manufacture to disseminate written information concerning the safety or effectiveness that is not described in the labeling only if, among other things, it is not "false or misleading" 21 C.F.R. § 99.101(a)(4). Moreover, information can be considered false or misleading, "if, among other things, the information includes only favorable publications when unfavorable publications exist..." 21 C.F.R. § 99.101(a)(4). The Lap-Band® Defendants marketing statement that there is an only 9% total complication rate not only contradicts the information they gave to the FDA, and is contradicted by numerous medical studies, some of which are described herein, the medical article they cite to support contention of a 9% total complication rate's lead author, Dr. Paul O'Brien, has received funding from Lap-Band® Defendants, and was the National Medical Director of a Texas based True Results Clinics which launched an extensive television marketing campaigns for the Lap-Band® and had a vested financial interested in promoting the effectiveness of the Lap-Band®.

238. As a result, the representations, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part

of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

239. The Lap-Band® did not conform to the representations made by Lap-Band® Defendants.

240. At all relevant times, Plaintiffs used the Lap-Band® for the purpose and in the manner intended by Lap-Band® Defendants.

241. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its hidden increased risks and its unreasonable dangers.

242. Lap-Band® Defendants' breaches constitute violations of state common law.

243. The breach of warranties described herein were a substantial factor in bringing about Plaintiffs' injuries. As a direct and proximate result of Lap-Band® Defendants' acts and omissions, Plaintiffs were implanted with the Lap-Band® device and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;
e. punitive or exemplary damages in the amount of $3 Million; and
f. such other relief and further relief as this Court may deem just and proper.

COUNT IX
MISSOURI PRODUCTS LIABILITY ACTION
(Against Lap-Band® Defendants)

244. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

245. Missouri Revised Statute § 537.760 governs claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, or labeling of any product.

246. As used in section 537.760, the term "products liability claim" means a claim or portion of a claim in which the plaintiff seeks relief in the form of damages on a theory that the defendant is strictly liable for such damages because: (1) Lap-Band® Defendants, wherever situated in the chain of commerce, transferred a product in the course of their business; and (2) The product was used in a manner reasonably anticipated; and (3) Either or both of the following: (a) The product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, and the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold; or (b) The product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the plaintiff was damaged as a direct result of the product being sold without an adequate warning.

247. Lap-Band® Defendants designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Lap-Band®, including the Lap-Band® devices that were implanted into Plaintiff.

248. As discussed above, Lap-Band® Defendants have a continuing duty to monitor their product post-approval and to discover and report to the FDA any complaints about product

performance, adverse events, and any health consequences of which they know or should have known about which may be attributable to the product. Lap-Band® Defendants also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Lap-Band® device.

249. Lap-Band® Defendants had a parallel duty under Missouri Revised Statute § 537.760 to exercise reasonable care in warning the public, including Plaintiffs and/or Plaintiffs' physicians, about the dangers of Lap-Band® that were known or knowable to Lap-Band® Defendants at the time of distribution.

250. Lap-Band® Defendants' failure to adequately and timely report adverse events is a violation of the federal requirements and state law.

251. Specifically, Lap-Band® Defendants breached these duties and violated federal law by and including, inter alia:

A. 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a), because as discussed in detail above, Lap-Band® Defendants failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device erosion, erosion of the stomach and/or esophagus and infection, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

B. 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Lap-Band® Defendants failed to report new clinical investigations and/or scientific studies concerning the Lap-Band® device about which Lap-Band®

Defendant knew or reasonably should have known about indicating increased risk of bad erosion, re-operation and band failure;

C. 21 C.F.R. § 820.198 because Lap-Band® Defendants failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints of, but not limited to, device migration, device erosion, erosion of the stomach wall and infection and other quality problems associated with the Lap-Band® device.

D. 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Lap-Band® Defendants (1) failed to appropriately respond to adverse incident reports, including but not limited to, device erosion, stomach erosion and infection and re-operation, which strongly indicated the Lap-Band® device was malfunctioning or otherwise not responding to its Design Objective Intent, and (2) Lap-Band® Defendants continued to sell Lap-Band® into the stream of interstate commerce when they knew, or should have known, that the Lap-Band® was malfunctioning or otherwise not responding to its Design Objective Intent.

E. 21 U.S.C. §§ 360(q); 360(r) because Lap-Band® Defendants created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Lap-Band® in order to convince physicians and patients to use Lap-Band® over other methods of weight loss, thereby gaining market share.

F. 21 C.F.R. § 814.80 because the Lap-Band® device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

G. 21 U.S.C. § 352(q) because Lap-Band® Defendants created and distributed false and misleading advertising for Lap-Band® which is a "Restricted Device" because Lap-Band® is not a safer and more effective method of weight loss than alternative methods, evidenced by the numerous reported adverse events consisting of serious injuries, by the numerous Lap-Band® studies consisting of reporting that patients who undergo the Lap-Band® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the unreported complaints contained in Lap-Band® Defendants' complaint files

H. 21 C.F.R. § 814.39 and Lap-Band® Defendants' PMA June 2001 letter because Lap-Band® Defendants failed to submit and/or timely submit a PMA supplement to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the numerous reported and unreported adverse events consisting of serious injuries, by the numerous Lap-Band® studies consisting of reporting that patients who undergo the Lap-Band® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the unreported complaints contained in Lap-Band® Defendants' complaint files.

252. If Lap-Band® Defendants had met their duties under the above mentioned federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiff and Plaintiff' physicians of the increased risks and serious dangers associated with Lap-Band® in time to have lessened or prevent Plaintiff' injuries.

253. Plaintiffs and Plaintiffs' physicians would not have used and recommended the Lap-Band® procedure for weight loss if the FDA had been fully and adequately informed of the material and necessary information to be able to communicate the safety risks related to Lap-Band®.

254. Additionally, if Lap-Band® Defendants had met their duty under the above mentioned federal regulations and parallel state laws, such information would have been made available to Plaintiffs and Plaintiff' treating physician, as discussed above, which would have allowed Plaintiffs' treating physician to properly and/or timely diagnose the cause of Plaintiffs' pain and health problems as being the Lap-Band® device.

255. Since Lap-Band® Defendants failed to meet their duty under the above mentioned federal and parallel state laws, Plaintiffs and Plaintiffs' treating physicians did not know and had no reason to know that Lap-Band® was causing or likely to cause Plaintiffs' injuries.

256. As such, Plaintiffs and Plaintiffs' treating physicians could not properly and/or timely diagnose or prevent the cause of Plaintiffs' injuries, which caused and/or contributed to Plaintiffs having to endure prolonged and unnecessary pain and suffering.

257. As a direct and proximate result of one or more of the above listed violations, and parallel state laws, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. compensatory damages according to proof;

c. costs of litigation;

d. post-judgment interest;

e. punitive or exemplary damages in the amount of $3 Million; and

f. such other relief and further relief as this Court may deem just and proper.

COUNT X
VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT
(Against Lap-Band® Defendants)

258. Plaintiffs incorporate by reference all paragraphs of this Petition as if fully set forth herein.

259. The Missouri Merchandising Practices Act ("MMPA"), Mo. Ann. Stat. §407.020 provides, in part, as follows:

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce...in or from the state of Missouri, is declared to be an unlawful practice...Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

260. Plaintiffs purchased and used the Lap-Band® device for personal use and thereby suffered ascertainable losses as a result of Lap-Band® Defendants' actions in violation of the State of Missouri consumer protection law, Mo. Rev. Stat. §§ 407.010 et seq.

261. At all relevant times and as described herein, Lap-Band® Defendants knowingly directly and indirectly represented to the Plaintiffs, the Lap-Band® device was a safer and more effective method of weight loss and weight stabilization when compared to other alternatives, and that when used, it was not defective.

262. Lap-Band® Defendants' advertising, promotions, and representations contained described herein were false and misleading and constituted unfair or deceptive acts and practices declared unlawful by the MMPA.

263. Lap-Band® Defendants' advertising, promotions, and representations described herein were false and misleading and constituted unfair or deceptive acts and practices which were not approved by the FDA and/or the FDA premarket approval process.

264. Lap-Band® Defendants knowingly made false representations for the purpose of deceiving Plaintiffs, and Plaintiffs' physicians regarding the safety and efficacy of Lap-Band® in order to ensure the marketability and success of Lap-Band®, which was in violation of the MMPA.

265. Lap-Band® Defendants engaged in the unlawful practices set forth in this Petition in the sale of merchandise in trade or commerce.

266. Lap-Band® Defendants' false statements as set forth in this Petition are material in that they relate to matters which are important to consumers or are likely to affect the purchasing decisions or conduct of consumers, including Plaintiffs' regarding the Lap-Band®.

267. Lap-Band® Defendants engaged in the false statements and in the concealment, suppression, misrepresentations and/or omission of the material facts described within this Petition with the intent that others, such as Plaintiffs, their physicians, and/or the general public would rely upon the false statement and concealment, suppression, misrepresentation and/or omission of such material facts and purchase the Lap-Band®.

268. The false statement and the concealment, suppression, misrepresentation and/or omission of the material facts described herein, had the capacity to, was reasonably foreseeable that it would, and did so deceive.

269. Plaintiffs would not have agreed to undergo the Lap-Band® procedure absent the false statements and/or the concealment, suppression, or omission of the aforementioned material facts.

270. Plaintiffs suffered actual and ascertainable loss of money and damages as an actual and proximate result of Lap-Band® Defendants' intentional misrepresentations and concealment of material facts.

271. Lap-Band® Defendants' conduct described herein actually and proximately caused Plaintiffs to suffer damages as described throughout this Petition.

272. Plaintiffs are entitled to recover their actual damages, attorneys' fees, and other equitable relief, pursuant to Missouri law, including Mo. Ann. Stat. § 407.025.

273. Furthermore, Lap-Band® Defendants' unlawful conduct set forth in this Petition was and is wanton, willful and outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiffs and warrants an award of punitive damages to deter Defendants, and others in similar circumstances, from committing such actions in the future.

WHEREFORE, Plaintiffs pray for judgment against the Lap-Band® Defendants, jointly and severally, in an amount in excess of Twenty-Five Thousand Dollars ($25,000), awarding:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
b. compensatory damages according to proof;
c. costs of litigation;
d. post-judgment interest;
e. punitive or exemplary damages in the amount of $3 Million;
f. Attorney's fees; and
g. such other relief and further relief as this Court may deem just and proper.

COUNT XI
MEDICAL MALPRACTICE
(Against Defendant Scott)

274. Plaintiff Hackman incorporates by reference the other paragraphs of this Petition as if fully set forth herein.

275. At all times mentioned hereinafter, the surgeon-Defendant Scott was and is a physician duly licensed to practice medicine under the laws of the State of Missouri. During relevant times herein, Defendant Scott maintained offices for the practice of the profession in St. Louis County, Missouri, Boone County, Missouri and currently maintains an office for the practice of the profession in the State of Missouri.

276. At all times mentioned, the surgeon-Defendant Scott professed and held himself out to the public and to Plaintiff Hackman as being skilled, careful and diligent in the practice of his profession as a physician. Specifically, the surgeon-Defendant held himself out as having the degree of skill and learning to successfully perform bariatric surgery and any treatment, surgical procedures, and care associated therewith.

277. On or about September 16, 2016, Defendant Scott attempted to perform a laparoscopic partial gastrectomy with gastrojejunostomy. Before Defendant Scott attempted this procedure, Defendant Scott was aware that Plaintiff Hackman had a history of laparoscopic gastric band placement with subsequent erosion and removal. Defendant Scott's history also wrongly stated Plaintiff Hackman has undergone a Roux-en-Y gastric bypass. This history indicated, or should have been indicated, to Defendant Scott that attempting a laparoscopic partial gastrectomy with gastrojejunostomy would present a high level of anatomic and surgical complexity as well as significant risk of complications.

278. In and around January 11, 2016, Defendant Scott performed an esophagus gastroduodenoscopy which showed significant distortion of the distal esophagus and an eroded silastic ring suggesting a previous vertical banded gastroplasty and not a Roux-en-Y gastric bypass. Defendant Scott also noted at that time multiple fistulous tracts in the stomach. These findings compounded the anatomic and surgical complexity of the planned laparoscopic partial gastrectomy with gastojejunostomy.

279. The correct anatomy of the vertical banded gastroplasty with eroded silastic band were not appreciated by the preoperative esophagogastroduodenoscopy and/or communicated to Plaintiff Hackman prior to surgery through informed consent. The distortion of the distal esophagus was noted, but not communicated as a significant complicating factor to Plaintiff Hackman prior to surgery. A history of Lap-Band® placement, erosion, and removal compounds this complexity. The level of these complexities and risk of injury were not adequately explained to Plaintiff Hackman prior to surgery, including the high risk of failure and the likelihood of injury to structure and post-operative complication leaks and injury.

280. The misidentification of Plaintiff Hackman's previous operations and known anatomic complexities were not fully appreciate by Defendant Scott leading directly to misidentification of anatomy, esophagus tear, and subsequent leak related to the repair of the esophagus tear.

281. Plaintiff Hackman, at all relevant times herein, placed herself under the care of and employed the Defendant Scott as a physician and surgeon.

282. Defendant Scott acted negligently by failing to act in compliance with the standards of due care, skill, and practice required by members of their profession, *inter alia*, in:

A. Negligently and carelessly failing to investigate the anatomic and surgical complexity of Plaintiff Hackman prior to her February 25, 2010 surgery;

B. Negligently and carelessly misidentifying Plaintiff's Hackman's previous operations;

C. Negligently and carelessly misidentification Plaintiff's Hackman's anatomy;

D. Negligently and carelessly failing to communicate to Plaintiff Hackman all known risks prior to her February 25. 2010 surgery, including the high risks of failure, the high risks of injury to her anatomy; and the high risks of post-operative complications;

283. As a direct and proximate result of Defendant Minkin's negligence, Plaintiffs were caused to suffer injury and harm as described herein.

WHEREFORE, Plaintiffs, prays for judgment against surgeon-Defendant, for a fair and reasonable sum in excess of Twenty-Five Thousand Dollars ($25,000), and for such other relief this Court deems just and proper.

COUNT XII
MEDICAL MALPRACTICE
(Against Defendant Minkin)

284. Plaintiffs incorporate by reference paragraphs the other paragraphs of this Petition as if fully set forth herein.

285. At all times mentioned hereinafter, the surgeon-Defendant Minkin was and is a physician duly licensed to practice medicine under the laws of the State of Missouri. During relevant times herein, Defendant Minkin maintained offices for the practice of the profession in St. Louis County, Missouri, and currently maintains an office for the practice of the profession in the State of Missouri.

286. At all times mentioned, the Defendant Minkin professed and held himself out to the public and to Plaintiff Hackman as being skilled, careful and diligent in the practice of his profession as a physician. Specifically, the Defendant Minkin held himself out as having the degree of skill and learning to provide care and treatment to Plaintiff Hackman, including determining what, if any, medical procedures could be used to treat Plaintiff Hackman's morbid obesity. In providing care and treatment to Plaintiff Hackman, Defendant Minkin failed to determine that Plaintiff Hackman had eroded silastic bands from a previous vertical banded gastroplasty through adequate investigation, and/or failed to appreciate the significance of Plaintiff Hackman having a previous vertical banded gastroplasty with eroded silastic band left in the area of her stomach before implanting a Lap-Band® device in Plaintiff Hackman. Defendant Minkin failed to determine through adequate investigation and/or failed to appreciate that eroded silastic bands from a previous vertical banded gastroplasty, was a contradiction for placing an additional foreign body, namely a Lap-Band® devise, in and around same area of Plaintiff Hackman's anatomy.

287. In and around February 25, 2010, Defendant Minkin implanted a Lap-Band ® in Plaintiff Hackman. Defendant Minkin implantation of a Lap-Band® over a previous failed vertical banded gastroplasty with eroded silastic bands still inside Plaintiff Hackman was outside the standard of care and caused , or contributed to cause, the injuries to Plaintiff Hackman described herein. Defendant Minkin provide continuing medical care for and treatment essential to Plaintiff Hackman's recovery up through at least February 16, 2017.

288. Plaintiff Hackman, at certain times herein, placed herself under the care of and employed the surgeon-Defendant Minkin as a physician and surgeon.

289. The surgeon-Defendant Minkin acted negligently by failing to act in compliance with the standards of due care, skill, and practice required by members of their profession, *inter alia*, in:

A. Negligently and carelessly failing to appreciate the anatomic and surgical complexity of Plaintiff Hackman prior to her February 2010 surgery;

B. Negligently and carelessly misidentifying Plaintiff's Hackman's previous operations;

C. Negligently and carelessly misidentifying Plaintiff's Hackman's anatomy;

D. Negligently and carelessly failing to communicate to Plaintiff Hackman all known risks prior to her February, 2010 surgery, including the high risks of failure, the high risks of injury to her anatomy; and the high risks of post-operative gastrointestinal leaks;

E. Negligently and carelessly implanting a Lap-Band® device in and around the area of a failed vertical banded gastroplasty with bands still implanted within Plaintiff Hackman.

290. As a direct and proximate result of surgeon-Defendant's negligence, Plaintiffs were caused to suffer injuries and harms as described herein.

WHEREFORE, Plaintiffs, prays for judgment against surgeon-Defendant, for a fair and reasonable sum in excess of Twenty-Five Thousand Dollars ($25,000), and for such other relief this Court deems just and proper.

COUNT XIII

LIABLITY OF DEFENDANTS DES PERES HOSPITAL AND ST. LOUIS BARIATRIC SPECIALISTS, LLC AGAINST PLAINTIFF HACKMAN

291. Plaintiff Hackman incorporates the allegations contained in all previous paragraphs.

292. Under the principals of respondent superior, actual agency and/or apparent agency, defendants Des Peres Hospital and St. Louis Bariatric Specialists, LLC is vicariously liable for the negligent acts and omissions of Defendants Scott and Minkin which lead to the injuries suffered by Plaintiff Hackman.

293. That as a direct and proximate result of the Defendants Des Peres Hospital and St. Louis Bariatric Specialists, LLC., Plaintiff Hackman was focused to suffer Lap-Band® erosion of the gastric band hardware, epigastric pain, distal esophagus, peptic ulcer disease, severe abdominal bloating, multiple gastric fistula, gastroparesis and surgery to remove the eroded Lap-Band® and subsequent surgeries in an attempt to alleviate injuries caused by the Lap-Band® and insertion and removal of feeding devices.

294. That as a direct and proximate result of the neglect of Defendant Des Peres Hospital and St. Louis Bariatric Specialists, LLC, Plaintiff Hackman incurred medical, hospital, health care service treatment in reasonable amount and will become further obligated for necessary hospital, medical and health care treatment in reasonable amounts in the future.

WHEREFORE, Plaintiff Hackman, prays for judgment against Defendant Des Peres Hospital and St. Louis Bariatric Specialists, LLC or a fair and reasonable amount in excess of $25,000.00, and for judgement interest, together with her cost and for such other relief as the Court deems necessary and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, respectfully demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, and all such other relief as the Court deems just and proper as well as:

A. compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, and great pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

B. for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C. for specific damages according to proof;

D. for Punitive and Exemplary damages in the amount of $3 million (excluding medical Defendants);

E. for post-judgment interest as allowed by law;

F. for the costs of these proceedings; and

G. for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial.

Respectfully submitted,

THE DYSART LAW FIRM, P.C.

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